

EXHIBIT F

REPORTER'S RECORD
VOLUME 1 OF 1 VOLUMES
TRIAL COURT CAUSE NO. DC-14-04220

CAROL CAVNESS) IN THE DISTRICT COURT
vs.)
TERESA KOWALCZYK, M.D.,)
HUNT MEMORIAL HOSPITAL DISTRICT)
CHARITABLE HEALTH FOUNDATION) DALLAS COUNTY, TEXAS
d/b/a HUNT REGIONAL HEALTHCARE)
FOUNDATION and HUNT REGIONAL)
MEDICAL CENTER AT GREENVILLE,)
BAYLOR HEALTHCARE SYSTEM,)
JOHNSON & JOHNSON and ETHICON,)
INC.) 95TH JUDICIAL DISTRICT

TRIAL ON THE MERITS, MORNING

On the 30th day of September, 2015, the
following proceedings came on to be held in the
above-titled and numbered cause before the Honorable,
Judge Ken Molberg Presiding, held in Dallas, Dallas
County, Texas.

Proceedings reported by computerized stenotype
machine.

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PROCEEDINGS

(Outside presence of the jury)

THE COURT: Everyone ready?

MR. PARRISH: Your Honor, we have a couple
of housekeeping matters to address briefly this morning.

THE COURT: All right.

MR. PARRISH: Two should be very easy, and
one I'll just give you a heads up on. And they relate --
the final thing I wanted to bring up with you just related
to some arguments on the depo designations. First thing I
wanted to take care of is we have our jury questionnaires
that we wanted to return to the Court.

THE COURT: All right. Real good. I
appreciate that.

MR. PARRISH: Certainly. May I approach?

THE COURT: I'll take them.

MR. PARRISH: Thank you.

MR. EDWARDS: Good morning.

THE COURT: Do y'all have your jury
questionnaires?

MR. CAPSHAW: I think we shredded them
already, Your Honor.

THE COURT: Double check.

MR. CAPSHAW: I will, but I know I shredded
all the ones I have.

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1 MR. PARRISH: Your Honor, the second matter
2 that I wanted to bring up just very briefly has to do with
3 the plaintiff's counter designations on Philippe Zimmern
4 and this is an issue that Mr. Edward and I discussed
5 yesterday.

6 They inadvertently omitted an answer from
7 their counter-designations. I'm not fussing at them
8 about that, but the answer does raise an objection that
9 I just wanted to get on the record. And specifically,
10 the question is asked beginning at page 81, line 9
11 through 19 -- excuse me, page 81, line 16.

12 Question: Dr. Zimmern, in your practice
13 that some of your -- some of your patients who have had
14 mesh completely removed still suffered from pain long
15 after the mesh has been removed, but the cause of the
16 pain was the mesh.

17 Answer: That is correct. Can I add one
18 point? This was not just my opinion. This was the four
19 people's writing this article opinion.

20 And that answer at 81, 21 through 23 was
21 something that we would have objected to based on the
22 previously filed motion in limine, fifth motion number
23 one and number four dealing with other articles under
24 401 being not relevant because it was an article dealing
25 with TVT exclusively, and Dr. Zimmern didn't have

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1 any experience with PROSIMA™. So we would renew those
2 particular motions and also assert the objection under
3 401 and 403.

4 THE COURT: Response?

5 MR. EDWARDS: This is the first I'm hearing
6 about this because I thought we were willing to include
7 it, so what I would say is we are referring to the
8 article, and that is an article -- the answer relates to
9 that article that Dr. Zimmern actually prepared with the
10 three guys he says that have the consensus of the authors
11 writing that article.

12 THE COURT: All right. But he's saying
13 that this is a different product.

14 MR. EDWARDS: But it's still deals with
15 synthetic mesh and also the Polypropylene heavyweight mesh
16 that's actually included, the same with TVT as well as the
17 PROSIMA™ device. And that's his experience as to -- as to
18 what he has experienced with patients that he sees when he
19 removes that mesh from them.

20 THE COURT: Well, I can see that the --
21 that the difference pointed out doesn't really matter in a
22 certain part of this case. I mean, it's probably
23 Polypropylene mesh that is allegedly the culprit, at least
24 in a certain context. There's PROSIMA™ or whatever. I
25 don't think I can quite slice it that thin.

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1 I can -- I can see with respect to
2 certain other arguments where it might be dissimilar,
3 but with certain other allegations made by the
4 plaintiffs it is similar, preclusive and travels across
5 the board, and the difference being in the -- in the
6 category he's looking at, the PROSIMA™ -- would be
7 different than probably, and I don't know what they're
8 talking about exactly in the article. But the PROSIMA™
9 would probably be different in a pore size and perhaps
10 weight. Yet it would be similar in the context of other
11 issues involved in the case but after degradation and
12 curling and stretching and whatever.

13 So in any event, the objection's
14 overruled.

15 MR. PARRISH: Thank you, Your Honor.

16 Finally, one last thing, and we don't
17 want to take up too much of the time this morning with
18 this, but I did want to bring it to the Court's
19 attention. With respect to our designations of Jimmy
20 Sanders, which we intend to play later today, plaintiff
21 has lodged certain objections to our designations.

22 MR. EDWARDS: And I have those here, Your
23 Honor.

24 MR. PARRISH: And I have also prepared our
25 response to those, and I will give Your Honor a copy of

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1 the deposition and --

2 THE COURT: Sanders objections by the
3 plaintiff?

4 MR. PARRISH: That's correct. And I --
5 I've included our response --

6 THE COURT: Okay. Real good.

7 MR. PARRISH: -- within that document, so
8 that you can take a look at that on a break, if you have
9 time.

10 MR. EDWARDS: Your Honor, I don't want
11 to -- just submit there are a lot, but I'd like to explain
12 something. Of the lawyers up here, I was the only one at
13 that deposition, and there is -- the biggest issue, as you
14 will note, this -- our objection is that the defense
15 lawyers prepared a chart, but they look almost like an
16 index that corresponded with their notebook.

17 And they kept referring to that chart.
18 That chart is a summary prepared by the defense lawyers,
19 not by doctor -- not by the physician's assistant, Jimmy
20 Sanders, therefore we believe it lacks foundation, calls
21 for speculation. It's hearsay, and it was only
22 created for litigation.

23 THE COURT: And Sanders is being tendered
24 as an expert?

25 MR. BLANKENSHIP: He's a treater.

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1 MR. EDWARDS: Treater.

2 MR. BLANKENSHIP: He's a PA, Judge.

3 THE COURT: So what is this so-called

4 summary of?

5 MR. EDWARDS: They went through the medical

6 records, and part of that summary within that is treatment

7 by other physicians, Dr. Gray and Dr. Thurman, that -- or

8 the PA, Mr. Sanders, did not even treat her at that time.

9 What the -- what the defendants are doing is putting that

10 chart, and they are saying, well, here's her 101st

11 visit, here's her 98th visit.

12 That chart actually includes phone

13 calls from the doctor's office, visits in which

14 Mr. Sanders did not see her. And so it's very

15 prejudicial in that they are saying look at all these

16 visits that we pulled out of the records to show that

17 Ms. Cavness would continue to go to the doctor over and

18 over and over again.

19 And so we just feel that it's very

20 prejudicial and that the reference to this the chart is

21 hearsay because it's nothing that Mr. Sanders prepared.

22 It was prepared by the lawyers and sent to him, and then

23 they came and met with him and discussed that chart.

24 THE COURT: So the -- so I'm trying to grab

25 onto the objection here. I mean, if they hadn't used the

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1 chart and they'd just done it without a chart, it'd be

2 okay?

3 MR. EDWARDS: Well, they could have

4 referred to the medical records.

5 MR. PARRISH: Well, and, Your Honor, if I

6 may respond, and then I'll try to go in reverse order.

7 First of all, with respect to the last point, the summary

8 was prepared, but it was authenticated by Mr. Sanders.

9 During the deposition, he had the medical records present.

10 He checked the medical records during the deposition, as

11 you will see when you go back and review the deposition

12 testimony.

13 THE COURT: Who is Sanders?

14 MR. PARRISH: He's a physicians assistant.

15 MR. EDWARDS: Physician assistant --

16 THE COURT: Okay.

17 MR. EDWARDS: -- at Hunt.

18 MR. BLANKENSHIP: Sandknot, Dr. Sandknot's

19 office.

20 MR. PARRISH: That's what it is now, but

21 it's Hunt Partners. It's disclosed.

22 MR. EDWARDS: He saw her from 2000 -- her

23 being Ms. Cavness, 2000 to 2011, and then there was a

24 break in time when he saw her in 2014, did some well woman

25 exams when she would get sick.

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1 THE COURT: So this includes stuff that

2 goes --

3 MR. PARRISH: Back to 2006, I think, maybe

4 2005 on.

5 MR. EDWARDS: 2004. Yeah it goes all the

6 way back to 2000, Bill.

7 MR. PARRISH: But he had the records in

8 front of him. He authenticated the chart. You'll see

9 that in his deposition. We have the medical records that

10 have been already been filed as business records

11 affidavits, so nothing's not in evidence.

12 THE COURT: Going on from that, what -- is

13 there any other objections?

14 MR. EDWARDS: There -- well, in addition to

15 the chart, there's quite a few references to collateral

16 source and workers' comp, which we've objected to, and

17 you'll note that and meet the objections.

18 MR. PARRISH: In response to that, there's

19 nothing regarding payments from workers' comp. The

20 plaintiff has already testified that she was injured on

21 the job, so nothing about any payments made in any of our

22 designations.

23 MR. EDWARDS: They --

24 THE COURT: What -- what is -- I mean,

25 yeah, I've got to look at it. But what is the relevance

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1 of 2005 or whatever it is? I mean, are we talking about

2 stuff like she went in because --

3 MR. PARRISH: There is injuries on the job,

4 and just to -- to illustrate the medical history, the

5 symptoms of pain experienced by the plaintiff, it's not

6 something brand-new just associated with this mesh. She's

7 had lots of physical injuries. She's had lots of

8 medication prescribed over the years.

9 THE COURT: Was there any tie in here to

10 the -- to the current?

11 MR. EDWARDS: Well, Your Honor, no. And if

12 you read the -- my cross of Mr. Sanders, I go -- I walk

13 him through, did you find any problem with her vaginal

14 wall or support? He says no. They -- what they're trying

15 to establish is that she had chronic depression, chronic

16 vertigo, basically went to the doctor all the time.

17 If you read Jimmy Sanders, our counters,

18 he says, she did not have chronic depression, she did

19 not have chronic vertigo. She -- and if it would -- if

20 she would have had that, I would have put that in the

21 medical record. You do not see anywhere in her medical

22 records from 2000 to 2011 anything that he said was

23 chronic -- a chronic condition. After he saw her again

24 in 2014, it was chronic pelvic pain.

25 And so what they're trying to establish

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1 is that she has vertigo. She has --
 2 THE COURT: How would that be any different
 3 than if they tried to show you were a chronic defendant?
 4 MR. EDWARDS: Well, Your Honor, my response
 5 is, if you'll recall the testimony of Ms. Pickel, her
 6 daughter, she said that she was basically in great health
 7 before she had this surgery, so it goes to discount that
 8 testimony.
 9 THE COURT: Well, she probably lied to her
 10 mother at some time during her life, too. So.
 11 MS. DOWNS: Your Honor, could I add one
 12 other thing that we think it -- makes it very relevant,
 13 and that would be expert testimony to which this will be
 14 important because her physical history and a few
 15 orthopedic injuries that she had added a load to her
 16 pelvic floor and primed her for the injury that she had in
 17 April of 2012.
 18 This series of information that's coming
 19 in from the past of her medical history is all directly
 20 related to that. It's something that we need for
 21 our expert testimony.
 22 THE COURT: Did somebody say all of that is
 23 relevant to -- I don't know. I see this fairly
 24 frequently, and it always puzzles me why, if they can --
 25 if you can go after her for having other injuries that may

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1 or may not be some way related, even remotely related to
 2 something of issue, why can't they -- they go into other
 3 things that your client's done?
 4 MS. DOWNS: Well, Your Honor, I think
 5 there --
 6 THE COURT: Or why can't they go into the
 7 other lawsuits and settlements and --
 8 MS. DOWNS: Well, our position --
 9 THE COURT: -- and fines by the federal
 10 government? And why can't they go into all of that? Why
 11 can't they -- why doesn't that just open the door, if
 12 we're going to attack somebody for every ding in their
 13 person, whether it be their real person or corporate
 14 person, why can't I just let all that in?
 15 MS. DOWNS: Well, Your Honor, I think that
 16 those two things respectfully are different categories
 17 with Ms. Cavness.
 18 THE COURT: I'll read it.
 19 MS. DOWNS: Thank you.
 20 MR. PARRISH: Thank you, Your Honor.
 21 MR. BLANKENSHIP: Thank you.
 22 THE COURT: We ready?
 23 MS. GALLAGHER: Your Honor, I have one
 24 housekeeping matter.
 25 THE COURT: Yes.

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1 MS. GALLAGHER: When Dr. Sepulveda's
 2 testifying at some point this morning, I'm going to ask
 3 him to comment on some actual MRI films and a defecography
 4 MRI -- work on that word before we get the jury in here --
 5 and so they're actually MRI images. Can we dim the lights
 6 for a couple of minutes, so he's talking about --
 7 THE COURT: Yeah, just let me know.
 8 MS. GALLAGHER: Okay. Thank you.
 9 THE COURT: All right. Line them up,
 10 Robert.
 11 THE BAILIFF: All rise for the jury.
 12 (Jury in)
 13 THE COURT: Be seated. Good morning.
 14 JURY PANEL: Good morning.
 15 THE COURT: You may call your next witness,
 16 Ms. Gallagher.
 17 MS. GALLAGHER: Thank you, Your Honor.
 18 At this time, we'd call Jaime Sepulveda.
 19 THE COURT: All right. Mr. Sepulveda if,
 20 you would come forward and stand before the Court and
 21 raise your right hand, please. I know it's a little
 22 crowded up there. You -- that's fine. All right.
 23 (Witness sworn)
 24 THE COURT: If you'll be seated up here and
 25 please speak into that microphone directly.

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1 **DR. JAIME SEPULVEDA,**
 2 having been first duly sworn, testified as follows:
 3 **DIRECT EXAMINATION**
 4 **BY MS. GALLAGHER:**
 5 Q. Got to pull that towards you. You can pull the
 6 mic towards you, Doctor --
 7 A. Right here.
 8 Q. -- just so that everybody can hear you. Good
 9 morning, Doctor. Will you introduce yourself to the
 10 jury, please.
 11 A. My name is Jaime Sepulveda.
 12 Q. What do you do for a living?
 13 A. I'm a gynecologic surgeon, a pelvic surgeon.
 14 Q. Where do you practice?
 15 A. In Miami, Florida.
 16 Q. Doctor, I've asked you to come testify about
 17 several subjects in front of this jury today; is that
 18 right?
 19 A. Yes.
 20 Q. And are you going to be addressing for them the
 21 cause of Ms. Cavness's pain?
 22 A. Yes, I will.
 23 Q. And what pain syndromes she actually has?
 24 A. Yes.
 25 Q. Now, before you give the jury your opinions,

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1 let's back up a little and tell them a little bit about
2 you. All right.

3 You do not have a Texas accent. Where
4 are you from?

5 A. I am -- I'm Puerto Rican. I was born,
6 raised in Puerto Rico.

7 Q. And how long were you in Puerto Rico?

8 A. I was there until I came for my fellowship at
9 University of Miami.

10 Q. Let's back up a little. Why did you become a
11 urogynecologist?

12 A. First, I became a gynecologist. And, um, I --
13 I was -- I was the first doctor in my family, but I was
14 around health care, and my mother was a social worker for
15 the postpartum ward at my hometown in Bonsai, and as a
16 single mother, she took me to the -- to the hospital, and
17 I just -- I just grew up in that environment and
18 eventually went on a scholarship to boarding school and
19 University of Puerto Rico, a medical school there.

20 Q. Outline your educational background for the
21 jury from time you went to medical school on.

22 A. Then from medical school, I did a fellowship on
23 molecular pharmacology. I was attracted by bench work,
24 and I did a fellowship there. It's -- it's a -- it's a
25 year in the -- in the lab and then also at the University

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1 and fellowships and internships had you had at that
2 point?

3 A. I've had my four years of -- of university, my
4 four years of medical school, and my uro -- uro
5 fellowship and my four years of residency.

6 Q. Before you ever got to the United States?

7 A. Yes.

8 Q. All right.

9 (Phone ringing in courtroom)

10 Q. And then when you got to the United States, did
11 you go into private practice immediately?

12 A. No, no.

13 Q. Tell -- tell the jury a little bit about your
14 work background and educational background once you got
15 to the states?

16 A. Well, like -- like most people that finish
17 medical school, I didn't come to Miami with a whole lot.
18 I -- I -- I had a good position, an academic position,
19 and it was a position working on the medical school and
20 working on -- on the hospital and having the opportunity
21 to do research and having the opportunity to do surgery
22 and.

23 And I -- I -- that's when we started
24 the -- we got all together at the -- we had a meeting at
25 the NIH colorectals, urologists, gynecologists. We have

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1 of Puerto Rico. And then I -- I did some more research
2 on -- on -- on renal cells and flow cytometry and cell
3 cultures. And then I went to the clinical aspect of
4 medicine through my residency in obstetrics and
5 gynecology.

6 Q. When you said that you were doing pharmacology
7 work, that's the study of medications?

8 A. Yeah. We -- we were -- what I did is optimized
9 the -- the system to test different medications,
10 different solutions on -- on cells.

11 Q. And so that was actually work in a laboratory?

12 A. Yes.

13 Q. And then you mentioned some other fellowships
14 that you did.

15 A. Well, after I did OB/GYN and -- and an OB/GYN,
16 I like the surgical aspect. I like the -- the
17 interaction with -- with the female patient and in
18 OB/GYN. Then I did -- I went to University of Miami, and
19 it was at a time in which we were starting the
20 subspecialty of urogynecology, which is known today as
21 female pelvic medicine reconstructive surgery.

22 Q. All right. Let's back up a little. When did
23 you get to Miami?

24 A. On 1990.

25 Q. And up until 1990, how many years of education

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1 all this meeting, and we say, okay, there's a consensus
2 to create this subspecialty. And I was one of the first
3 probably 25, 25 doctors starting that.

4 Q. And you said at a meeting at the NIH.

5 A. Yeah. We --

6 Q. What is the NIH?

7 A. -- the National Institute of Health. My
8 mentors at the -- at the university send me there, and
9 they trusted that I was going to bring a report to create
10 that subspecialty.

11 Q. And let's talk about that subspecialty. You
12 said you and -- and about 25 other doctors started it?

13 A. Yeah. I think it was -- it was -- the group
14 wasn't larger than 25. We cannot take the credit for --
15 for creating that subspecialty. It was there for us, but
16 by all the work that all the other gynecologists through
17 the years have done. But we -- we gave a structure. We
18 actually made it in a way that someone can actually study
19 and refer to it.

20 Q. And what's the difference between gynecology
21 and urogynecology, what you do?

22 A. You know, when -- when we -- when we started
23 looking at a name, we didn't come up with the name.
24 The -- there were doctors, they'd say, okay, this is
25 going to be urogynecology. Other places, they call it

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pelvic surgery. And both terms really did not include the scope of what we were looking at.

We -- we didn't want to create a subspecialty that would just concentrate in surgery, that would -- but that would serve the female patient in general in those special needs of prolapse and incontinence and pelvic pain and -- and all the different dysfunctions that could happen to these patients.

Q. When did you actually enter private practice?

A. I -- I finish in 9 -- '92 at the university, and then I went to South Miami Hospital, and -- and the -- I was the first one doing what I -- doing pelvic -- pelvic floor work at that hospital in 1993.

Q. Did -- are you board certified?

A. Yes, I am.

Q. What are you board certified in?

A. I am board certified in obstetrics and gynecology. Then I have the -- I'm board certified -- I have the subspecialty board certification on female pelvic medicine. I'm proud to be on -- have been on the first group that completed this -- this certification.

And I'm also -- have a certification at -- type of board certification by Herman & Wallace Pelvic -- Pelvic Institute, which is called the pelvic

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floor rehabilitation certification.

Q. So is it fair to say you're triple board certified?

A. Yeah, if you want to refer as triple board.

Q. All right. Triple board. And you mentioned that you were in the first group to receive the subspecialty certification in female pelvic medicine and reconstructive surgery. When was that board first offered?

A. The -- it was offered three years ago.

Q. And were you in the very first group to actually take and pass that certification?

A. Yes, I was.

Q. And then you also mentioned that you have a certification in pelvic floor therapy?

A. Yeah. It's an -- in pelvic floor rehabilitation, we don't -- I'm not a physical therapist. I don't see a doctor. I have a -- I got the certification on pelvic floor rehabilitation.

Q. And what does that involve, pelvic floor rehabilitation?

A. You know, it's -- before this, all the boards were for -- were for physical therapists. But there's -- there's this gap about -- from -- from the physical therapy area to the medical aspect, so up to -- up to

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about three years ago, two years ago, actually, there was no way to get a board certification in pelvic floor rehabilitation, in something that I could tell my patients, yeah, someone -- someone actually tested me and shows that I'm proficient in giving pelvic floor rehabilitation.

And this is a key part of seeing these patients, being aware of that pelvic floor rehabilitation. So what you do is that you submit your case list. There's a board that approves it, and they ask the -- they tell you you can sit and take the exam. And that's what I did. I took the exam, and -- and after I was approved, even though ended up being a lot of work, it was a five-hour exam, standardized exam, but the most rewarding thing is that once you pass the exam, you know that someone validated that you know what you think you know.

Q. Okay. Do you belong to any professional groups?

A. Yes, I do.

Q. Tell the jury what some of those are.

A. I -- I belong to American Urological Association. I'm a fellow of the American College of Obstetricians and Gynecologists, and I'm a fellow of the American College of Surgeons. I'm a fellow of both

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colleges, and -- and I'm a member of numerous pelvic floor societies, International Urogynecologic Association, American Urogynecologic Society, International Incontinence Society.

Q. What does it mean to be a fellow of the two colleges?

A. Well, once you -- once you pass your board, then you have to be in good ethical and moral standing, and they -- they evaluate your application, and you become a fellow. You're able to place all those letters that you see after you -- after you go and see a doctor, but you see all those letters afterwards, yes. They -- they say that you are -- you are -- that you are a fellow in good standing.

Q. You are also on the National Board of Medical Examiners?

A. That was -- that was my initial certification. I'm -- I'm -- I'm --

Q. You've also served on some committees at your hospitals?

A. Yes.

Q. And one of those things that you're still involved with is the Chairman of the Medical Arts Surgery Center?

A. Yes.

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Q. What does that involve at your hospital?

A. This is the surgery center at the hospital, and what -- what I -- I mean, obviously I do surgery, and I practice medicine and bring my surgery -- my patients for surgery. But what I also do is that I over -- I look over credentialing. It means I -- I look at doctors that apply to have privileges at the hospital to work at the hospital.

I -- I look at credentialing. I look at the -- at the operations of the place in terms of safety. I -- I'm the liaison between the physicians and the organization. And I -- when joint commission comes in for accreditation and they want to talk to a doctor, I'm the one that talks to joint commission for the people that accredit the facility.

Q. You've also served on the Surgical Review Committee?

A. Yeah. Part of -- you don't become chairman of -- of the surgery center from when you leave -- when you leave your fellowship. You have to prove yourself through different areas and be devoted to -- to surgical review committees where you look at surgery outcomes, you look at results, and then you -- I also -- I'm the credentialing on all these different committees.

Q. Have you -- are you currently involved with

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clinical research?

A. Yes, I am.

Q. Tell the jury a little bit about that.

A. I am -- I head as a principal investigator the fibroid registry. The -- it's a registry for uterine fibroids at my hospital, and I also head the pelvic floor or pelvic health study group. The pelvic health study group is -- is a group of doctors. It's all -- all -- all pelvic floor related, colorectal surgeons, urologists, radiologists, physical medicine specialists, physical therapists, all the doctor -- neurologists, gastroenterologists.

All these doctors that have to do with pelvic floor, we get together every other month, sometimes every three months if there's a summer in the middle. And we look at cases, and we bring cases. We discuss the cases, and everybody gives their own perspective on -- on these cases, and we come up with therapy solutions.

Q. And when did that start?

A. We -- we started that about two years ago. That's a continuing medical education activity, so it's -- we have to actually get the certification for it to be a continuing medical education activity.

Q. Have you also taught courses in medicine?

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A. Yes, I have.

Q. Tell the jury what a couple of those were.

A. I -- I have -- I have taught courses within the industry and without the industry in both -- in both areas. And through all those courses, I've also traveled the United States, and I have help to put together different -- different departments.

Just -- just to mention a few, I helped to put together the pelvic floor -- the pelvic surgery section at the University of Puerto Rico with -- with a good friend of mine who is the Chief of that division. I have traveled to Columbia, put together an experimental surgery lab over there and years ago. So I -- I -- all over this time, I have been tracked to probably about a thousand surgeons that I have seen operate or they have seen me operate.

Q. And have you published on chronic pelvic pain?

A. Yes. I -- I publish in one of the proceedings in the past a long time ago.

Q. And have you published articles on a number of different topics?

A. Yes.

Q. Doctor --

MS. GALLAGHER: May I approach, Your Honor?

THE COURT: You may.

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(Approaching)

Q. (BY MS. GALLAGHER) Doctor, let me hand you what is marked DX10660 and ask you if you can identify that, please.

A. That's my -- my CV.

Q. And does your CV contain a lot more details than what we've gone over today about your background and experience?

A. Yes.

MS. GALLAGHER: Your Honor, at this time defendants offer DX10660.

MR. MATTHEWS: We have no objection.

THE COURT: Admitted.

Q. (BY MS. GALLAGHER) That's fine. You can leave it there.

Doctor, you've been practicing medicine for a long time now?

A. It's 26 years.

Q. What are some of the things that you are most proud of from your career?

A. I'm -- I'm really, really proud of -- of the -- of what we put together -- what I put together when I -- at the very beginnings when I was starting in my community and there was no place for -- for a woman to go to a facility that would be dedicated to the care of

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1 pelvic floor disorders.
 2 Q. And so what did do to you?
 3 A. Well, first I convinced the hospital to finance
 4 it, and that -- I took a loan, and then put it together
 5 with the -- with the best -- best equipment that I could
 6 see. And I recruited the right personnel, all my -- the
 7 nurses and the assistants, recruited them, and made it --
 8 made it a -- a simple place where they could come in and
 9 they wouldn't have to be waiting in a urologist office
 10 among all these guys treating their prostates or they --
 11 or they would not have to be in an OB/GYN office with
 12 baby's running around. They could just get there and
 13 take care of their pelvic floor problems.
 14 Q. And what was that called?
 15 A. At that time, it -- we call it the Miami
 16 Urogynecology Center.
 17 Q. And when did you open that?
 18 A. It was about 1994.
 19 Q. And was that the first such facility in the
 20 whole state of Florida?
 21 A. That -- yeah. That was the first -- that was
 22 the first. And after that, there were a few -- few
 23 people fortunately reproduced that, and that's -- I'm
 24 good with that.
 25 Q. And so now there are other such centers around

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1 the United States?
 2 A. Yes, yes.
 3 Q. What's your other -- what's your favorite thing
 4 to do besides taking care of patients in your profession?
 5 A. I -- I like to interact with my colleagues. I
 6 may travel and go see them do surgery. I may -- they may
 7 come and see me do surgery. And I just -- I just like
 8 that -- that intellectual interaction with all my -- all
 9 my colleagues. I have developed very good relationship
 10 with my -- with my -- with my colleagues over the years,
 11 and I like that interaction.
 12 Q. Do you teach other surgeons how to do surgery?
 13 A. I -- I do. I -- I -- I do not teach others at
 14 a student level. I -- I -- it's mostly skills, finesse
 15 skills that now I can learn from a lot -- sometimes I
 16 watch a surgeon do certain things, and I -- I acquire
 17 those -- those skills.
 18 Q. Let's talk about your clinical experience.
 19 Tell the jury what your average day is like when you're
 20 at work.
 21 A. Well, get -- get to the office, look at -- I
 22 have -- obviously I look the night before what I -- what
 23 I have. And on Mondays, I -- Mondays I have all my -- my
 24 major cases. Mondays is all my large cases.
 25 Q. What is a large case?

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1 A. The -- the big reconstructions, that's --
 2 that's on Monday. And then on Tuesday, I see -- I see
 3 patients the whole day, and I talk to patients, do
 4 consultations. On -- on -- on Wednesdays, I do my -- my
 5 outpatient surgery. On Thursdays, I -- I see more
 6 patients.
 7 On Friday, I take the afternoon off. I
 8 work only the morning doing procedures in my office.
 9 Most of my meetings for -- as medical -- as medical
 10 director happen around 6 o'clock, so when I finish my
 11 surgeries, I -- on my patients, I go there.
 12 Q. What kind -- I'm sorry.
 13 A. So that -- that -- that's it, essentially it.
 14 Q. You said on Mondays you do reconstructive
 15 surgeries. What types of surgeries are you doing?
 16 A. I do the open surgeries, robotic surgeries. I
 17 do vaginal surgeries. I do the approaches for pelvic
 18 organ prolapse, vaginal prolapse, bladder and rectal
 19 prolapses, and -- and patients that have had recurrent
 20 prolapse. I treat them, too.
 21 Q. And then you said on Wednesdays you do your
 22 outpatient procedures. Tell the jury what kind of
 23 procedures you're doing with that.
 24 A. It's mostly incontinence proceedings.
 25 Q. Now, as part of your practice, do you read

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1 diagnostics?
 2 A. Yes, I do.
 3 Q. Tell the jury what a diagnostic is.
 4 A. Well, we -- in our facility, we have the -- the
 5 pelvic -- pelvic rehabilitation section, and one of my --
 6 of my colleagues takes care of -- of that -- that area,
 7 and we devise the protocols. Then there is a diagnostics
 8 section that includes testing for urinary incontinence,
 9 for fecal incontinence, imaging, ultrasounds of the
 10 pelvic -- of the pelvic floor within the office.
 11 And -- and -- which is not an office
 12 anymore. It's more like -- like a whole -- the whole
 13 facility. It's -- and we have a -- we do cystoscopies,
 14 too, on the diagnostic section. And then we have the
 15 actual consultations with the patients, place where we
 16 see patients.
 17 Q. Do you actually read the films from ultrasounds
 18 and MRIs?
 19 A. Yes, we do right at the office with the
 20 ultrasound, and we also do in the pelvic floor board.
 21 Q. And is that something you do on a regular
 22 basis?
 23 A. Yeah. I do it now on a regular basis after my
 24 radiology colleagues have taken me through -- through a
 25 few -- a few -- a few of the images.

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1 Q. Now, when did you first encounter Ethicon?
 2 A. I went to -- I went to the first activity with
 3 Ethicon when they invited me to see sling procedures in
 4 the -- in the lab, in a specimen lab.
 5 Q. What is a sling procedure?
 6 A. It's a procedure for urinary incontinence.
 7 Q. And you said to a -- in a lab, a specimen lab?
 8 A. Yes. It's -- a specimen lab is when you're --
 9 learning anatomy in first year of medical school, you go
 10 to a specimen lab. They have -- they have a cadaver
 11 where you have to study ahead of time where you're going
 12 to look into, and we're not taking -- talking about a
 13 full -- a full cadaver. We're talking about a section.
 14 And this is persons that have donated
 15 their body to science, and they would -- they -- they
 16 allocate this -- these specimens for -- to different
 17 facilities, to different -- different labs where you can
 18 learn.
 19 Q. And why were you interested in going to these
 20 cadaver labs?
 21 A. I was -- I was mostly interested on the -- on
 22 the activity of with being able to dissect, being able
 23 to -- to study the anatomy where I work every day.
 24 When -- once -- once you leave your first year of medical
 25 school, for many doctors that's the end of their training

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1 on pelvic floor anatomy.
 2 And I -- and I saw -- I always was
 3 interested, and I knew that -- so I knew that if I was
 4 doing surgery, there's nothing like knowing your anatomy
 5 when you're doing surgical procedure, nothing substitute
 6 that knowledge. I mean, yeah, you have to be skillful.
 7 You have to be delicate with the tissues. You have to
 8 do all things -- all things that we know that are right
 9 for the good healing.
 10 But also you -- you need to know where
 11 you're going. You need to know what -- you need to know
 12 where you -- what you're doing in terms of the space.
 13 Q. So was this additional training that you had
 14 once you got to Miami?
 15 A. It's -- it was -- it was an opportunity to
 16 get -- to get into the cadaver lab. Unless you are back
 17 to first year of medical school, you don't get that
 18 opportunity again. In other words, you have your surgeon
 19 doing surgery on you after all these years of training,
 20 and that surgeon hasn't had the opportunity to go back to
 21 the -- to the -- to the lab and say, okay, what is it
 22 that I'm really doing here? What -- am I really doing
 23 what I think I'm doing on these proceedings?
 24 Q. Did you eventually start teaching at these
 25 cadaver labs for Ethicon?

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1 A. Yeah. I think that everybody caught -- caught
 2 word of my enthusiasm in my -- my devotion to develop
 3 this as -- as a tool where we could learn not just about
 4 the device but also about the anatomy.
 5 Q. And did you eventually actually put together
 6 manuals for training in these cadaver labs?
 7 A. Yes, I did.
 8 Q. And we'll talk a little bit more about that
 9 later.
 10 MS. GALLAGHER: Your Honor, at this time,
 11 we offer Dr. Sepulveda as an expert in urogynecology,
 12 pelvic floor -- pelvic floor dysfunction, and pelvic
 13 muscle rehabilitation.
 14 THE COURT: Hearing no objection, very
 15 well. You may proceed.
 16 MS. GALLAGHER: Thank you.
 17 Q. (BY MS. GALLAGHER) All right, Doctor. You've
 18 done some work in this case?
 19 A. Yes. Yes, I have.
 20 Q. And tell the jury what you've done in order to
 21 get ready to give them or to prepare to formulate your
 22 opinions and then give them to the jury today.
 23 A. Well, I have -- I have seen multiple records
 24 from -- from all the providers, and I have seen the --
 25 the records from the providers, the records from the

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1 hospital. I have seen operative reports. I have seen
 2 imaging. I have seen MRIs, ultrasounds. I have seen
 3 deposition transcripts. I have seen exhibits from --
 4 that have been given to -- I have read articles again
 5 that I have read in the past, and I have had to read
 6 them -- read them again and done -- which is -- which is
 7 actually very, very good. I get to polish my knowledge,
 8 and -- and these are the documents that I have examined.
 9 Q. And are we compensating you for your time that
 10 you've spent doing this?
 11 A. Yes.
 12 Q. About how many hours do you think you've spent
 13 in total reviewing the medical records, looking at the
 14 depositions, re-familiarizing yourself with the
 15 literature, educating me about the medicine in this case?
 16 What's your estimate of the total amount of time you've
 17 spent?
 18 A. This is the first time that I go through all
 19 this, so have to be about 150 hours.
 20 Q. And what are you charging per hour?
 21 A. I charge \$500 an hour.
 22 Q. And is that whether you're reviewing records or
 23 testifying?
 24 A. Yeah. It's -- it's -- it applies to
 25 everything. There's -- there's -- there are other

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1 scales, but I just -- it applies to every hour that I
 2 spent.
 3 Q. All right. Now, have you been in Dallas
 4 several days this week?
 5 A. Yes, I have been.
 6 Q. When did you get in?
 7 A. I got in on Sunday.
 8 Q. And why have you been here since Sunday?
 9 A. Because I have -- I had to meet with you and go
 10 over the slides.
 11 Q. On Sunday.
 12 A. I had to -- I had to actually see that and see
 13 that and meet with -- with the team about the images that
 14 I -- that I felt were relevant, and -- and you-all -- we
 15 all worked very hard, prepared well, so I had to
 16 prepare to be efficient on this.
 17 Q. And were you here in the courtroom when
 18 Dr. Margolis testified yesterday and the day before?
 19 A. Yes. Yes, I was.
 20 Q. And why were you in the courtroom while he
 21 testified?
 22 A. Because I never -- I never done it, and I
 23 wanted to make sure that when I come in here, I could do
 24 it right.
 25 Q. Did you also --

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1 (Laughing)
 2 Q. -- want to the listen to his opinions?
 3 A. Yeah. I got to listen to his opinions.
 4 (Laughing on jury)
 5 Q. But it's mostly so you could see how this
 6 process worked?
 7 A. Yes.
 8 Q. All right, Doctor. I want to talk to you now
 9 about -- I'm going to call this anatomy 101. I went
 10 through this with the jury in opening, but I don't think
 11 anybody who's really qualified to explain this to them
 12 has done it.
 13 MS. GALLAGHER: Your Honor, may I have
 14 Dr. Sepulveda step down and talk about something?
 15 THE COURT: You may.
 16 Q. (BY MS. GALLAGHER) Doctor, if you'd come on
 17 down, please.
 18 A. Yes.
 19 MS. GALLAGHER: This is what we used in
 20 opening, David.
 21 Q. (BY MS. GALLAGHER) All right, Doctor.
 22 A. Go get my pointer.
 23 Q. Let me get it to you, so you can -- and,
 24 Doctor, our blue lady over here, would you just explain
 25 the anatomy and where the various organs are that we'll

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1 be talking about today?
 2 A. Well, we'll be -- we'll be talking about the
 3 bladder. We'll be talking about the vagina. There's
 4 no -- no uterus in here. And this is the rectum, and
 5 you -- the perspective here is we're looking at someone
 6 from the side. We --
 7 Q. So is the --
 8 A. -- that is standing like this.
 9 Q. And this is the front over here?
 10 A. Yeah.
 11 Q. Okay.
 12 A. These -- this bone here, this bone here is the
 13 pelvis. This is the bone that you feel when you press on
 14 the pelvis.
 15 Q. And then over here on our colored picture,
 16 explain to the jury what this is. What is that?
 17 A. This is the presentation of a rectocele, and
 18 this is -- the vagina, and this is the division. This
 19 tissue divides from the bottom up, divides the tissue
 20 between the rectum and the vagina. And not surprisingly
 21 we call it the rectovaginal tissue.
 22 Q. And what causes -- so is this actually the
 23 rectum?
 24 A. Yeah. This is -- you -- you urinate through
 25 here, and this is -- you defecate through here. Just

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1 there's defecation comes right through here.
 2 Q. And so is this actually part of the rectum that
 3 is coming out of the vagina?
 4 A. Yes. It's not a normal -- not a normal part.
 5 This is a prolapsing part. It's protruding through the
 6 vaginal tissue.
 7 Q. And what generally causes a prolapse?
 8 A. It's a variety of conditions, but in essence,
 9 it is the weakness of the tissue. Each individual have
 10 different strength of tissue, and there's -- there's a
 11 weakness or tissue becomes delicate and in here. And
 12 they -- it can also be the support of the vagina is lost.
 13 There's -- there are muscles that run all around here,
 14 and when those muscles become flaccid or break, the
 15 prolapse comes in.
 16 Q. And can you get a prolapse gradually?
 17 A. You -- you can get it gradually, or you can get
 18 it quickly.
 19 Q. And when you get it quickly, what generally
 20 causes that?
 21 A. The -- the most recent reason for that is
 22 accumulation of stress in that -- in that area, and
 23 it's -- it's that the tissue become indurated, they
 24 become contracted. The muscle becomes hard, sometimes
 25 doesn't have the normal oxygen supply, doesn't have

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1 the -- all the fluids, and it loses elasticity and on the
2 southern force just breaks. In other words, it's hanging
3 by a few threads, and then it breaks, and then we see the
4 prolapse.

5 Q. What breaks?

6 A. The -- the muscle -- the muscle -- the muscle
7 breaks.

8 Q. All right. Let me get another board up here
9 and see if you can explain this. And, again, we start
10 with our -- thank you, Doctor. We start with our blue
11 lady, and this is some -- this is the anatomy without a
12 prolapse, right?

13 A. Yes. That -- in here, we -- we just remove the
14 organs, and -- and this is as -- as -- as complicated as
15 this would be, when you dissect a cadaver, when you're in
16 the lab, it looks exactly -- exactly like this. That was
17 my first one, and when I saw this diagram, and you see
18 all these fibers of muscles. This is not just a
19 representation. This is a very accurate presentation of
20 the muscles.

21 Now, what you have is that this -- these
22 muscles act like a hammock. If you -- obviously this is
23 part of my spine, and this area here is my hips, and
24 those muscles act like hammock. When you're walking
25 around, they hold things together. So through here,

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1 A. No, no. This is -- this is when you get on --
2 dissect everything out, you're able to identify these
3 muscles.

4 Q. About how many muscles are there in the pelvic
5 floor in total?

6 A. There are 650 muscles in the whole system, and
7 most of them are concentrated in the -- in the pelvis and
8 in the neck.

9 Q. So 650 in someone's entire body?

10 A. Entire body.

11 Q. And how many or what percentage are in the
12 pelvic floor?

13 A. There are easily 150, and there are variations,
14 and there are different distributions and how high you go
15 on your anatomy boundaries, but it takes -- it's easily
16 about 150.

17 Q. Okay. We're not going to talk about 150.

18 A. No, no, won't put you through that, no.

19 Q. All right. So we're going to focus on these
20 muscles down here. Now, you said that if somebody has an
21 acute or a sudden prolapse that the muscle has broken.

22 A. Yeah. The --

23 Q. Explain to the jury using the diagram what
24 you're talking about.

25 A. Well, the -- there I have mentioned two things

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1 through here we have the opening of the -- opening to
2 the -- to the rectum. And through here, we have the
3 opening to the vagina. And this division here
4 corresponds to this area here on the division between
5 the vagina and the rectum.

6 But this essentially the muscles that
7 hold to the bone, so something that I all -- I always
8 mention when I'm teaching anatomy class is the closer
9 you get to the bone, the thicker the tissue gets. And
10 you -- you -- you may see that, those of you that --
11 when you're having a steak, you see that the muscle
12 holds right through your bone there with that -- with an
13 attachment, with a stronger attachment. That's what you
14 have. That's when you see right -- right here an
15 attachment of the muscle to the -- to the bone.

16 Q. And what are these back here?

17 A. These are more muscles. This -- this muscle we
18 call it the coccyx pubis muscle. There are tendons and
19 the tendons in this area, this is -- we call this the
20 sacrospinous ligament because it goes from the sacrum to
21 the spine. That's the sacrospinous ligament. And this
22 muscle is the coccyx pubis.

23 Q. All right. Now, we've got a representation
24 here of some of the muscles, but does that include all of
25 the muscles in the pelvic floor?

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1 that I -- that are -- that the tissue, how -- how -- how
2 elastic, how pliable, how strong the tissue is in -- in
3 here. And the other thing is that the tone and the
4 support that the -- that the muscles -- that the muscles
5 give.

6 So when you have just a tissue that just
7 becomes over time a little more elastic, you -- those
8 are the patients that come and tell me, well, I felt
9 something down there, then something a little later,
10 something at -- eventually, you know, it's going to
11 be -- at the beginning, I really ignore it. But I -- I
12 come to a point in which it's bothering me, so I need
13 you to tell me what it is, or they go to the doctor and
14 the doctor send them to me to see what -- what it is.

15 When you see -- when you see a sudden
16 quick appearance of the prolapse, there's a muscle that
17 broke. It's -- if you see suddenly, it broke.

18 Q. And how do you know that? Why -- explain to
19 the jury why that is.

20 A. Well, because that progressive -- progressive
21 enlargement is due to the pliability. The tissue become
22 very elastic. It just starts -- start distending under
23 the pressure. Right now when I'm talking, I'm putting
24 pressure in the abdomen. So the pelvic floor moves --
25 moves in. Every time we move, every time we go

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1 splinting, we go running, we exercise, we lift something,
2 that pelvic floor moves. And sometimes you see that that
3 comes -- that bulging comes out, and I -- they come up.
4 But when the muscle is broken, it just suddenly comes
5 out.

6 Q. And is that because there's nothing holding
7 these up anymore?

8 A. Right. Now, you don't have these -- we call
9 these the levator plait. This levator plait then
10 detaches from here, and by the way, you don't have to
11 detach the whole thing. You can detach only a few
12 fibers, and it's like when you have -- when you have a
13 curtain that is hanging and hanging from the rail,
14 sometimes those curtain, a few -- I don't know, it
15 happen -- it happens to me all the time, shower curtain,
16 a few come off, and you know that it sags. That's
17 exactly what happens to a muscle.

18 Q. And that's what leads the organ, in this case
19 the rectum, to sag into the vagina?

20 A. Well, once -- once they break, this opening is
21 not anymore a small opening. It just -- it just opens.
22 When it breaks, the hiatus, the opening of the organs, we
23 call it the hiatus, the hiatus opens up. That's --
24 that's what happens, just opens up and allows for the
25 organs to have other pressure come down.

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1 call the pubis. That -- that line, we call it the arcus.
2 It's like a beam.

3 Q. We call it the what?

4 A. Arcus.

5 Q. Arcus?

6 A. The arcus. It's like a beam, and that beam
7 holds the roof of the vagina.

8 Q. And you talked about the ischial spine. What
9 is that?

10 A. Here, that's this bone in support.

11 Q. And do you have one on each side?

12 A. One on each side. It's you -- that's -- that's
13 what -- how every time I teach someone how to -- I say
14 put your finger, you feel the ischial spine. That's the
15 landmark for everything else that you --

16 Q. What do you mean when you're teaching somebody
17 how to feel?

18 A. When I -- when I'm teaching a surgeon or I'm
19 teaching someone that says, okay, take -- give me a tour
20 of the pelvis, give me a tour of the pelvis, I -- and I'm
21 going to go ahead and tell them, okay, let's see for the
22 things that you feel quickly, and that is the ischial
23 spine.

24 Q. And you say when you feel. Is this through a
25 vaginal exam?

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1 Q. And let's talk about Ms. Cavness. Did she have
2 a muscle that broke?

3 A. Yeah. I --

4 Q. That --

5 A. -- that's exactly my opinion.

6 Q. Okay. And point out to the jury here the
7 muscle that you believe Ms. Cavness tore.

8 A. Based on the symptoms and based on what has
9 been documented on her records, I am -- I am -- I am
10 certain that that -- there's a muscle that broke right
11 around here, right here in the front. The attachment of
12 one of these muscles broke and --

13 Q. What do you -- oh, you want a marker?

14 A. Yeah.

15 Q. What color would you like?

16 A. Let's -- any color is --

17 Q. Got all sorts of colors.

18 A. I don't want to be --

19 Q. No, no, no, here. Let's use we'll -- hold on.
20 I can't get in this box. Let's see if green works.
21 Thank you.

22 A. And these are -- the fibers, when you look
23 closer, it looks -- it looks a lot nicer, these fibers.
24 And there's an attachment here that this area around here
25 goes from the ischial spine to behind this bone, which we

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1 A. Through the vaginal exam. That's the landmark,
2 and you feel it, and it's invariably about -- about 8
3 centimeters from the most -- from the outside in, and you
4 feel that. It's like an knuckle. It feels just like
5 your knuckle.

6 Q. So if you were coming -- if you were doing a
7 vaginal exam, you're coming through here?

8 A. Right.

9 Q. And this is what you're feeling?

10 A. Right. And then -- and then in here, it looks
11 really long, but it's about 8 centimeters.

12 Q. And why is it -- and why do you need landmarks?
13 What's the point?

14 A. You need -- you need to know where you're going
15 exactly. You need to know where -- I'm sorry. I think I
16 said I was going to cancel this.

17 Q. We don't like those exhibits. Okay.

18 A. So this -- this -- from here to here is
19 8 centimeters, and this is a landmark. You need to be
20 able to feel the landmarks. You're not going blind.
21 You're going by landmarks.

22 Q. And you say by going by landmarks. Then you
23 know what muscles and what organs, where they are based
24 on what you're feeling?

25 A. Right. I know that there are 10 centimeters

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1 from here to here, and I'm going to get -- and there I
2 know exactly where I'm going to feel it.

3 Q. And that's the anatomy that you learned first
4 in medical school and then later in these cadaver labs?

5 A. If you don't go back to a cadaver lab and you
6 just take what you learned in medical school -- in
7 medical school, it's -- it's just too shallow of a
8 knowledge.

9 Q. Okay.

10 A. You need to know -- know this.

11 Q. All right, Doctor. I'm going to -- I'm going
12 to move these back. You can go ahead and take your seat.
13 Claustrophobic, need space.

14 All right. Let's talk generally kind of
15 broad view about your opinions about what happened
16 with Ms. Cavness.

17 A. I -- I think that -- my opinion is that Ms. --
18 Mrs. Cavness had an acute injury to the pelvic floor. An
19 acute injury means something happened suddenly and
20 quickly.

21 Q. And she had an acute injury to her pelvic
22 floor, and that led to what?

23 A. That -- that led to the pain and that led to
24 the prolapse.

25 Q. And are the pain and prolapse the same thing or

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1 two different things?

2 A. They are two different conditions.

3 Q. And, Doctor, I'm going to be asking you about
4 your opinions today. And will you give those opinions
5 based on reasonable medical probability?

6 A. Oh, yeah, yes.

7 Q. That's a standard that we use. If I asked you
8 to give your opinions with a hundred percent accuracy,
9 could you do that?

10 A. I -- I think it's well-understood that
11 there's -- nothing is a hundred percent in life.

12 Q. And therefore there's nothing that's a hundred
13 percent in medicine?

14 A. No, absolutely not.

15 Q. All right. So we're talking about reasonable
16 medical probability. And you've come to these
17 conclusions based on what?

18 A. On the -- on the review of the medical records,
19 on the review of the history, on the images and the --
20 what each one of the surgeons not only documented in
21 their records but also spoke about, and finally the --
22 the imaging, the view of the -- of the images.

23 Q. And how about did you have an opportunity to
24 examine Ms. Cavness?

25 A. I did have an opportunity, yes, to

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1 examine Ms. Cavness.

2 Q. The jury knows we call those IMEs?

3 A. Yeah. It's called an independent medical
4 examination.

5 Q. And did you come to Texas to perform that
6 IME --

7 A. I did --

8 Q. Up here?

9 A. -- under -- under court order, under court
10 order. I --

11 Q. And are part of your opinions based on your
12 examination of Ms. Cavness also?

13 A. Yes.

14 Q. All right. So you said there were two
15 different things that were going on because of this acute
16 injury, the pelvic pain and the prolapse, right?

17 A. Yes.

18 Q. All right. So I'm going to talk about prolapse
19 first and talk about that, and then we'll talk about the
20 pain, all right, that Ms. Cavness has.

21 A. Yes.

22 Q. All right. So you've told the jury what
23 prolapse is and that Ms. Cavness had an acute injury.
24 What is the acute injury she had that caused the
25 prolapse?

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1 A. It was the -- by the way, defining -- defining
2 prolapse, I want to make sure that I clarify that
3 prolapse is when the organs -- the internal organs of the
4 pelvic prolapse come through -- through that area that we
5 have defined as a hiatus, as an opening. And is -- it's
6 a frightening thing when you actually see -- see that --
7 that there is a bulge coming through an area where you
8 have -- you have raised knowing that there's no bulge
9 that's going to be there.

10 Q. And what happened with Ms. Cavness that caused
11 that bulge or that prolapse?

12 A. The -- there was a -- a lifting either of a --
13 of a -- it was an injury either at work or lifting a pot
14 based on the -- on the review of the records. One of
15 those things made an acute force or produced an acute
16 force that followed immediately with the onset of pain
17 and prolapse.

18 Q. And where did you see this acute injury?

19 A. At -- I saw the -- the description of the
20 consequences of this injury. I saw the -- this in the
21 medical records from the visit to the emergency room
22 before she went to see Dr. Kowalczyk.

23 MS. GALLAGHER: T-Zady, will you please
24 pull up 10018.12, please.

25 Q. (BY MS. GALLAGHER) And, Doctor, this is -- do

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1 you recognize this record?
 2 A. I do.
 3 Q. And what is -- where is this record from?
 4 A. This is from the visit to the emergency room
 5 on -- on -- on April 20 -- 21st --
 6 MS. GALLAGHER: Is this in y'all's way?
 7 And --
 8 A. -- of 2012. I apologize for interrupting.
 9 Q. (BY MS. GALLAGHER) And we've highlighted
 10 portions of these records, but you've reviewed the entire
 11 record?
 12 A. Yes, I have.
 13 Q. There's stacks of them, right.
 14 A. Yeah.
 15 Q. There's a lot of records. And the pain level
 16 of 7 out of 10, what does that mean?
 17 A. 7 out of 10 -- out of 10 is a significant pain.
 18 It's -- that -- that's called a visual analog scale, and
 19 you see at one of the -- at one of the -- of the ends on
 20 the -- in the one, it's -- you have a little face with a
 21 with a little smile, it's content, and you have a 10 out
 22 of 10. There's a grimacing or actually crying with a
 23 pain. So that's -- that's the range, and this is from 0
 24 to 10. In the visual analog scale, she was 7.
 25 Q. When Ms. Cavness had this acute injury, was

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1 it -- this lifting injury, was there anything that had
 2 primed her for sustaining that kind of injury?
 3 A. I -- I do -- I do believe that patients that
 4 have had a history of injuries in other parts of their
 5 body, and you cannot put just one -- one -- one -- the
 6 pelvis as an isolated place. The pelvis is part of a
 7 person, and the person has different -- different areas,
 8 not just the pelvis, and different parts of the body
 9 can -- can be -- can be hurt. And when you have
 10 demonstrated consistently that you can hurt other parts,
 11 it's not surprising that you might have another injury
 12 elsewhere.
 13 Q. Why is it that if you injure your plait --
 14 injure yourself somewhere else that it can affect the
 15 pelvic muscles?
 16 A. The -- when you -- you can injure -- you can
 17 injure a leg on -- on -- a leg, and then as you walk
 18 around, you walk in balance, and your -- your muscles
 19 compensate for it. And unfortunately we also age, and we
 20 start putting more pressure in -- on one area over
 21 another and develop certain postures.
 22 We develop certain -- we call it gait,
 23 the way you walk. And all these things end taking a
 24 toll on the muscles. You adapt. We are -- our bodies
 25 are so smart that they keep adapting. They adapt to

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1 a -- in a way, and you can get injured, and you
 2 compensate and adapt in other ways. But that puts a
 3 load in -- more -- more load in other areas that were
 4 not -- were not intended to be there.
 5 Q. How about pregnancies, can that affect?
 6 A. Absolutely.
 7 Q. And did Ms. Cavness have pregnancies?
 8 A. She had -- she had two -- two babies.
 9 Q. How about smoking, can that affect your pelvic
 10 muscles?
 11 A. You know, that -- I -- I -- I can -- I can
 12 cannot encourage my patients more about stop poisoning
 13 theirself -- poisoning themselves with cigarette smoke.
 14 Q. How does that affect the muscles of the pelvis?
 15 A. There's -- nicotine -- and by the way,
 16 nicotine's just one of the components. You have -- and
 17 this is just general medical knowledge. You have carbon
 18 monoxide. You have all these different substances. At
 19 the moment that you take them, yeah, it gives you
 20 that reward on your -- on your brain receptors. It feels
 21 good. You -- you get a smoke, everything feels a little
 22 better, and it has -- maybe an analgesic effect in some
 23 way.
 24 But on the other side, it's acting
 25 physiologically by contracting your blood vessels,

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1 pro- -- putting profusion, thus profusion to the -- to
 2 the muscles. The muscles get dehydrated. They get what
 3 is called atrophic, they shrink. They -- they -- you
 4 have the -- the blood vessels again producing that --
 5 that changes, and the blood -- and those change in the
 6 blood vessels produce little clots that will pollute
 7 those vessels eventually and the -- it's a toxic effect.
 8 Q. So let's get back to Ms. Cavness. When she
 9 arrived to Dr. Kowalczyk's office I think that following
 10 Monday after she injured herself over the weekend, did
 11 she have options as to what to do with her rectocele?
 12 A. Yes, she -- yes, she did.
 13 Q. And what was -- what are some of the things
 14 that she could have done or not done to treat her
 15 rectocele?
 16 A. You -- you can -- you can observe it. You can
 17 always observe a rectocele, but I -- but I also
 18 understand that many times I have -- I spent more
 19 time reassuring my patients you're going to be okay
 20 observing this rectocele -- and we'll figure -- we'll
 21 figure this out.
 22 Q. And by observing, what do you mean?
 23 A. It's -- we call it -- observing is what we call
 24 it. In medicine, we call it watch -- watchful wait. You
 25 watch it; you wait. And that's -- that's -- that's an

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1 option. That's always an option for the patient. You
2 watch it; you wait. It's -- the other -- the other
3 option is to have -- to have surgery.

4 Now, once -- once the -- the prolapse
5 comes out -- and we're talking just about prolapse.
6 Once the prolapse comes out, we know that pelvic floor
7 exercises, pelvic floor rehabilitation may not be as
8 effective as when we have a prolapse holding -- holding
9 inside. In other words, you can have a little -- a
10 little prolapse in the inside, and you can -- you can
11 probably rehab those muscles and bring it back, assuming
12 obviously that there's no pain.

13 Q. And what option did Ms. Cavness choose?

14 A. The records show surgery.

15 Q. And was this -- is this a surgery that you
16 usually do the day -- the next day? Is it a
17 hurry-up-and-get-it-done surgery?

18 A. I -- I don't.

19 Q. When did she actually have surgery?

20 A. The -- the next day after she was seen by
21 Dr. Kowalczyk.

22 Q. And what time did she have that surgery?

23 A. Around 5 o'clock in the afternoon.

24 Q. Is that unusual?

25 A. That -- that is unusual. In my practice, it

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1 A. The tear, yeah.

2 Q. Now, you know, we all know that this surgery
3 was performed using PROSIMA™.

4 A. Yes.

5 Q. And was that a -- an appropriate decision
6 for Ms. Cavness to do various surgeries that she had
7 augmenting the PROSIMA™?

8 A. I -- I agree that that was the right decision
9 to use.

10 Q. And why is that?

11 A. Because there's certain criteria when you look
12 at the prolapse. I look at the description of the
13 prolapse, and there's certain criteria that is used to
14 it. And that criteria is developed through your history
15 and physical examination.

16 Q. And what is that criteria?

17 A. We -- we did a mnemonic. It's called RULES.

18 Q. RULES?

19 A. RULES. The way I teach it is RULES.

20 Q. R-U-L-E-S?

21 A. R-U-L-E-S. And the first R is to -- square R,
22 two Rs.

23 Q. Okay. What's the first R?

24 A. The first R is recurrence.

25 Q. What does that mean?

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1 is.

2 Q. And what is your understanding from your review
3 of the materials in this case, the medical records and
4 the depositions, as to why Ms. Cavness wanted surgery so
5 quickly?

6 A. I -- I think that the -- the big factor was the
7 pain, a 7 out of 10 pain.

8 Q. And do you usually have pain when you get a
9 prolapse?

10 A. Not unless you have an injury to the muscle.

11 Q. All right. Tell the jury why those are two
12 different things.

13 A. There -- these are two different things because
14 as we explained, there's the area of support in the
15 tissue, in the -- in the actual tissue that divides the
16 vagina from the rectum in this specific case. There's
17 the actual tissue. That's one thing with prolapse, it
18 becomes relaxed, and you get the prolapse.

19 Now, when you have a -- a -- a breakage
20 of the muscle, it's not only contributing to your
21 prolapse, it's not only making your organs come to the
22 outside, it's also hurting.

23 Q. And the hurting is from what?

24 A. From the -- from the injury to the muscles.

25 Q. The tear?

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1 A. And recurrence means that someone has repaired
2 this prolapse, and it came out. You're going to tell me,
3 well, Ms. Cavness didn't have -- didn't have a prolapse
4 before. You -- within recurrence, we include those
5 patients that have had a hysterectomy. The -- the only
6 organ in the whole pelvis that connects the anterior and
7 posterior portion, the lateral portion, and all the
8 ligaments is the uterus. The uterus connects everything.
9 It's central to the pelvis.

10 MS. GALLAGHER: May have him step down,
11 Your Honor?

12 THE COURT: You may.

13 Q. (BY MS. GALLAGHER) Doctor, explain to the jury
14 what you're talking about when you say it's the only
15 organ that connects to things.

16 A. It's only -- hysterectomy, there's the cervix.
17 There's the uterus here. Uterus -- this is the uterus
18 here. It connects the uterosacral ligaments. It
19 connects the part of the -- of -- the posterior part of
20 the -- of the connective tissue. It connects this. It
21 connects the anterior aspect of the connective tissue.
22 Everything is connected to this area right around here.

23 Q. And why is that important?

24 A. Well, in Mrs. Cavness, she -- she had a
25 hysterectomy before, so you don't -- you don't see -- you

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1 don't see a uterus.
 2 Q. No uterus.
 3 A. You don't see a uterus here. It's just the
 4 vaginal -- the vaginal wall, so part of the art for
 5 recurrence. Can I --
 6 Q. Yeah.
 7 A. -- the art of RULES -- the art of RULES is that
 8 previous hysterectomy. The other thing is the lack of
 9 rugae. Rugae are creases.
 10 Q. And that is R-U-G-A-E?
 11 A. Yes. Like -- like we -- we call -- there's
 12 words in Spanish that describes it, you know, like the
 13 creases here are -- we -- very similar, are rugae. But
 14 it's -- it's a rugae. And the rugae is, you see those
 15 little creases, and the creases are formed from the
 16 connective tissue, the tissue that gives support under
 17 the vaginal tissue.
 18 If you see that there -- when I examined
 19 the patient, if I see that there are rugae, I know I'm
 20 going to find some fiber connective tissue back there.
 21 Q. Okay. Wait, wait, wait. Can you draw Rugae?
 22 A. Yeah.
 23 Q. All right, Doctor.
 24 MS. GALLAGHER: If you would come -- may he
 25 step down, Your Honor?

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1 room, I can tell -- I can -- I know there's fiber
 2 connective tissue underneath. And the -- if I have fiber
 3 connective tissue, I can do a repair that does not
 4 require reinforcement using a graft.
 5 Q. What --
 6 A. I can just put absorbable sutures.
 7 Q. What is this fibrotic tissue? Tell the jury
 8 what that is.
 9 A. Fiber connective tissue --
 10 Q. Yes.
 11 A. -- is a dense tissue that gives support. It
 12 gives support to the -- to the -- to the vagina. If you
 13 really look at the covering of the vagina, it's a very
 14 soft, very soft tissue, very elastic tissue. But
 15 underneath what you have is that -- that tissue that
 16 gives the -- it's -- it's a contract -- it's a stiffer
 17 tissue on that area, and it has the nice rugae.
 18 So I know all I have to do is put
 19 together a few stitches, but when you go to the ope- --
 20 through the vagina, you don't see much of that.
 21 Q. Okay. So one was recurrence, right?
 22 A. Yes.
 23 Q. And then the rugae, which is here?
 24 A. Yeah.
 25 Q. Now, we're up to U. What is U?

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1 THE COURT: Yes.
 2 Q. (BY MS. GALLAGHER) Can you please draw some
 3 rugae for the jury?
 4 A. So when you examined the patient, this is the
 5 vulva, and the patient with and the patient without --
 6 with prolapse, you see that the lower aspect, the rugae.
 7 This is the opening. There are rugae here, but then once
 8 you get up here, you don't see -- you don't see much.
 9 There's nothing giving -- giving that rugae appearance.
 10 There's no tissue underneath giving the rugae.
 11 Q. So would this be -- if this is the -- this is
 12 the entrance to the vagina?
 13 A. Right.
 14 Q. And so this is like lines?
 15 A. Like lines right here.
 16 Q. And that -- the lines tell you what?
 17 A. It looks like -- it looks like -- like this
 18 paper.
 19 Q. Oh.
 20 A. And then when you have no tissue underneath, it
 21 looks flat.
 22 Q. And what's the significance of having tissue --
 23 yes -- or not having tissue underneath?
 24 A. Well, if I -- when I get back to the OR, to the
 25 operating room, when I take the patient to the operating

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1 A. The -- the --
 2 Q. That's a --
 3 A. It still belong --
 4 Q. -- r is square?
 5 A. -- to the rugae, to the rugae.
 6 Q. So we're at L?
 7 A. We're at L. And the L is the location, where
 8 is the prolapse located at.
 9 Q. And why is that important in your determination
 10 of whether or not you would use a product like PROSIMA™?
 11 A. Well, there's -- there's evidence published --
 12 evidence published in -- in anatomic and in the surgical
 13 anatomy in which we -- it's been proven that the tissue
 14 on the lower part, it confirms the observation that we
 15 have had for years. In the lower part, there's more
 16 fiber connective tissue. In the upper part, there's less
 17 fiber connective tissue.
 18 So it solves the dilemma that I found
 19 probably on the first 10 years doing surgery, which is I
 20 start dissecting and always found I have no tissue up
 21 there to put together. So you -- you end up putting
 22 fine sutures. The upper part of the vagina --
 23 Q. And just to orient the jury, when you're
 24 talking about the upper part, we're talking about up
 25 here?

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1 A. Yes.

2 Q. And so this is where you would see more rugae?

3 A. More dense fiber connective tissue in that area

4 around the perineum.

5 Q. What's the perineum?

6 A. The lower part.

7 Q. Down here?

8 A. The division between the vagina and the anus.

9 So once you get to the -- to the middle part, there's

10 less tissue, and once you get to the upper part, there's

11 almost no fiber connective tissue there, not much

12 support. What you have is the vaginal layer, and you

13 have the rectal layer or the peritoneal layer.

14 Q. And so if you're -- is that -- when you say

15 location, do you mean where the prolapse is actually

16 coming through?

17 A. Where the prolapse is actually at. Where's

18 my -- where's this prolapse being located? Is this in

19 the lower third, or is this in the upper third? This is

20 key in understanding what a posterior repair is. Not all

21 posterior repairs are the same.

22 You have posterior repairs that are done

23 in the lower third or in the upper third, and they're

24 two different types of surgery.

25 Q. And --

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1 You do it here, and since you don't have

2 a whole lot of tissue up here, patient comes back with a

3 recurrence. So part of the RULES, when you consider --

4 when you either contemplate using -- using a graft, the

5 L of the RULES is the location, where's my prolapse

6 located?

7 Q. E?

8 A. E is, is it external or internal? You operate

9 into someone that has a prolapse that is in the inside of

10 the vagina that they just feel occasionally, they respond

11 differently than someone that has a prolapse that comes

12 through the outside of the vagina.

13 Q. And is that the staging?

14 A. That's the staging, but instead of getting into

15 the -- the suit letter of the stagings, very simple, if

16 your prolapse is -- is inside, you have a lower rate of

17 recurrence with your repair. Is your prolapse --

18 prolapse is already outside, the recurrence is higher.

19 Q. And what's the last factor you considered?

20 A. The size, S. That's the final -- the final

21 letter on the -- the -- on the -- the size. You have a

22 prolapse that is larger than 2.5 centimeters, larger than

23 2.5 centimeters, and you have a higher rate of

24 recurrence. Why is that? How -- how we learn that? We

25 learned that from experience. 2.5 centimeters is the

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1 A. They all get placed on the bucket of the

2 posterior repair, and that's something that over time

3 we'll figure out and we'll have better -- better data and

4 better -- better studies on it.

5 Q. And where was Ms. Cavness's prolapse?

6 A. It's -- it extended. It had -- when you have a

7 detachment of the muscle, you just don't have a -- a

8 posterior -- posterior defect. You have an opening

9 hiatus. You have an opening post -- a dilated posterior

10 lower third, and it extends to the mid and upper -- upper

11 third. It extended through the whole extent.

12 Q. So if we're looking at our diagram, where would

13 her weakened tissue have been?

14 A. In the -- in the whole posterior.

15 Q. Do you have your pointer?

16 A. Yes.

17 Q. Okay.

18 A. Oh, yeah, yeah, yeah. It's -- this was open,

19 but this is the one that -- it's always a challenge, so

20 when we saw go back to location, to the L of RULES, the

21 location, upper third vaginal defects have a higher

22 chance of coming back, upper third. If you look at

23 the -- at these repairs down here, you repair them, and

24 the patient doesn't -- doesn't usually come back.

25 They're happy with it.

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1 actual opening. When you measure the gen- -- the genital

2 opening, when you measure -- measure the vulva opening,

3 it's 2.5 centimeters.

4 If you're prolapsed, it's bigger than

5 that. Obviously it has stretched outside. That's what

6 the S is, the size of the prolapse. Not all prolapses

7 are managed the same. So when you have -- you're

8 looking at a prolapse, you look at the RULES, and those

9 are the RULES that are going to determine how to counsel

10 my patient before I take her to the operating room.

11 Q. And apply these rules to Ms. Cavness --

12 A. In Mrs. Cavness --

13 Q. -- in April of 2012 when she went to see

14 Dr. Kowalczyk.

15 A. In April 23rd, 2003rd (sic), Mrs. Cavness

16 had the factor of the uterus being taken out. There --

17 there are -- what was described is different all the way

18 to the upper part. There's no actual description of

19 rugae, but I don't see rugae in the upper third when

20 someone comes with a detachment like that.

21 The location was described in the upper

22 two-thirds. The fact that it came external, she felt it

23 on the outside when she came to the emergency room, that

24 was the most frightening thing, and the -- the size of

25 the prolapse is associated to how external it is.

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1 Those -- all of them, when -- when I -- when I read the
2 medical records, I read the description of the operative
3 report, all of them are filled, the RULES.

4 Q. Now, are there -- were there other options
5 available other than PROSIMA™?

6 A. At -- at the moment -- moment of her -- of her
7 surgery, you could have done a native tissue repair. But
8 the native repair under these circumstances carry a
9 higher rate of recurrence.

10 Q. And just tell the jury what a native
11 tissue repair is.

12 A. Native tissue repair is when you take -- the
13 same tissues that broke down are going to put it
14 together. You take the same tissues that are behind the
15 prolapse, and you're going to rely -- after they broke,
16 you're going to rely on -- on -- on the scar tissue. We
17 call that scar tissue.

18 We hear scar tissue, scar tissue, and
19 scars are not always just as a scar. This -- when we --
20 the body's a lot smarter than that, and the body
21 produces fibrosis. So from now on, I may be referring
22 to it as fibrosis. That's the actual term, "fibrosis."

23 Q. And fibrosis meaning the scarring?

24 A. Fibrosis, yeah. But a scar is a scar, and we
25 can confuse it, but it's a fibrosis.

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1 because of this angle. So even if someone has the -- the
2 force or doesn't have the accuracy to go directly, it
3 cannot go any further than this. And this I -- I
4 measured with my fingers 10 centimeters. That's
5 essentially it, so --

6 Q. Now, the -- and so are you actually taking this
7 and putting it through the incision or the --

8 A. You put it right here. And -- and when this is
9 connected to an instrument that is -- we use for sutures,
10 this -- this right here, you can -- you connected it, and
11 then you identify the landmarks, that is the easiest way
12 to identify the body landmark, and once you identify the
13 body landmark, you slice it there. Take it out.

14 Q. And is that the ischial spine that you were
15 talking about?

16 A. Yeah. That's -- that's medial. We call it
17 medial. We -- medial is the -- to the middle. I do -- I
18 have my patient -- my patient here, and I want to
19 approach her -- her left side. I'm going to do it with
20 this. I'm going to have an instrument connected here.
21 In this angle, the instrument comes up like this, so I --
22 when I insert it, it cannot go any further than that --
23 any further than this in here.

24 It'll stop. It'll stop right there.
25 It'll stop outside. You cannot go any further than

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1 Q. Do you have a PROSIMA™ up there?

2 A. Yes, I do.

3 Q. Okay. Is that the actual size?

4 A. This is the actual size.

5 Q. All right. Can we have the --

(Off with co-counsel)

7 Q. And, Doctor --

8 MS. GALLAGHER: Your Honor, may he step
9 down?

10 THE COURT: He may.

11 Q. (BY MS. GALLAGHER) And, Doctor, what is this
12 that I'm handing to you?

13 A. This is the inserter, a similar inserter from
14 what was used to insert the PROSIMA™ on Mrs. Cavness.

15 Q. And is -- show the jury how that works.

16 A. Okay. So -- so the way it's -- it is designed
17 is it has a blunt end, so you -- I guess if someone has
18 the idea of penetrating anything, they will not be able
19 to. And -- and -- and it has that blunt end, and then
20 mesh is about 10 centimeters, and these 10 centimeters
21 you -- the vagina were really -- I don't know if I
22 defined that it was 12 centimeters, but I said on the
23 length of the vagina. And when -- when you insert it,
24 this design, this upper part here, when you place an
25 instrument to handle it, it doesn't let you go farther

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1 these 10 centimeters. I can -- I could pull my finger
2 and feel the tip, the ultimate PROSIMA™ as it was
3 inserted.

4 Q. And when you -- you can take your seat, Doctor.
5 When you insert it, are you actually putting it through
6 any muscles or --

7 A. No.

8 Q. -- stitching it?

9 A. No. You can -- you do not -- you do not have a
10 muscle that you insert it. That's -- the device doesn't
11 allow you to do it because it's square here in the -- in
12 the tip.

13 Q. Now, the jury has seen a picture of a Prolift,
14 which is much bigger, and it has long arms on it.

15 A. Right.

16 Q. And let me hand you this, and tell the jury
17 what this is and how this relates to a Prolift.

18 A. The -- the Prolift is, we're -- we're -- we're
19 placing it from another side. We're placing it from the
20 outside of the pelvis, and for patients to have a very
21 large -- large prolapse, I found it -- I found it very --
22 very useful, but it's a different procedure. It's a
23 larger procedure.

24 It's -- it's -- the anatomy sides are
25 different. The approach is different. This is a

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1 different -- different thing. This is a -- comes from
 2 the outside, and it looks -- it looks intimidating, and
 3 if you're -- if you're -- if you're not a surgeon
 4 obviously with a -- with a -- with -- with the expertise
 5 on -- on these type of procedures, you're not going to
 6 be using this, and --

7 Q. And does that actually -- is that designed to
 8 go through muscle?

9 A. This one goes through muscles. This goes
 10 through about -- about -- through about four or five
 11 layers of thick muscle, I mean, the -- the Prolift.

12 Q. Doctor, the jury has heard through Dr. Margolis
 13 that surgery with PROSIMA™ in the posterior or the back
 14 of the vagina is not superior to native tissue. Do you
 15 agree with that?

16 A. I do not agree with that.

17 Q. Why?

18 A. I do not agree with that for a few reasons.
 19 Number one, clinically, and clinically -- and when I say
 20 clinically, I mean in terms of surgical anatomy, we
 21 identify this -- this kind of things with RULES. We
 22 identify there's no -- no tissue in the upper part. I
 23 say clearly that not all posterior defects are the same.

24 Q. What does that mean?

25 A. You can have a lower defect. You can have a

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1 middle defect. You can have an upper defect, and the
 2 higher you go, you will not have that fiber connective
 3 tissue under -- under the vaginal epithelium. So that
 4 just validated -- that principle has got invalidated on
 5 the letter on the -- that became an article that over 600
 6 surgeons sent to the FDA in 2011.

7 That article, they made reference to four
 8 randomized control trials in which it is clear that
 9 these patients have a lower rate of recurrence when
 10 the repair of the posterior compartment is reinforced
 11 with a synthetic graft.

12 Q. The jury also heard from Dr. Margolis some
 13 comments about stiffness of the mesh. Is stiffness good?

14 A. I -- I -- I could not answer yes. I would have
 15 to explain that.

16 Q. Please do.

17 A. There's a degree of stiffness. There's a
 18 degree of stiffness that -- that you need, and it -- we
 19 use -- we use the term biomechanics, the movement, the
 20 biological movement of things. And the -- there's --
 21 when I explained before that these muscles have to have
 22 certain pliability and certain elasticity. It's like the
 23 shock absorber in a -- in a vehicle. You just -- it
 24 needs to -- it needs to move.

25 Q. And when you're saying "it," you're talking

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1 about what?

2 A. The muscle -- the muscle -- the muscles that I
 3 described before in the pelvic floor, it needs to move.
 4 When you're -- when you're doing squats, when you're
 5 exercising, when you're walking, when you're sneeze, when
 6 you're doing all these activities, they need -- they need
 7 to move like a shock absorber. If it's too stiff, it
 8 doesn't -- it doesn't move properly. That's the
 9 contracted muscle.

10 If it moves too much, the prolapse comes
 11 in. So there's -- there's a -- there's a degree of
 12 stiffness. Now, how do we grade that stiffness?
 13 There's -- there's evidence that -- of the stiffness
 14 index.

15 Q. What's a stiffness index?

16 A. Stiffness index, like any -- any index you hear
 17 all the Bloomberg and there's marketing index. Stiffness
 18 index is the actual quantification on how stiff something
 19 needs to be. That stiffness index, when you have -- when
 20 it was measured on a small population of patients, the
 21 stiffness index that was on the highest provided the
 22 best -- the best support for patients that have prolapse.

23 Now, there's -- like in everything else,
 24 there's no zero; there's no 100. You have to have
 25 something in the middle that would give that pliability,

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1 that elasticity. And that's what the -- those are the
 2 preliminary studies on stiffness index. They went
 3 further, and they saw that stiffness index can be
 4 correlated with quality of life symptoms for prolapse.

5 Q. Explain that.

6 A. Everything that we do translates into how we
 7 are going to feel. Nobody has surgery to feel worse.
 8 People have surgery to feel better. And that stiffness
 9 index, you need it. Otherwise, the patient will come
 10 back with a prolapse, will have that prolapse coming back
 11 at -- coming back and give symptoms.

12 It feels -- it feels -- over 26 years,
 13 I've learned that my patients that have those symptoms,
 14 they feel that bulging coming out, and that's not a good
 15 sensation for anyone.

16 Q. Dr. Margolis also talked about the heaviness
 17 and density of PROSIMA™. In your opinion, is the
 18 PROSIMA™ too heavy or too dense?

19 A. The -- at that time, they -- they -- the
 20 implant, the synthetic graft, with the largest body of
 21 evidence in the pelvic floor was the material used in
 22 PROSIMA™.

23 Q. How about Dr. Margolis's comment that PROSIMA™
 24 deforms or shrinks or contracts?

25 A. There's -- that -- that has been -- was

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1 addressed on the same communication that I just referred
2 to.

3 Q. What -- and tell the jury a little bit more
4 about that communication. Is that what I was asking?

5 A. Well, the communication was the FDA came in,
6 and there was a panel of about 12 people on the -- on
7 the -- on the FDA that say, listen, we have -- we have
8 gone through these studies, and based on what we're --
9 what we're seeing, there's no benefit on using -- on
10 using -- or there's no clear -- clear -- it was no clear
11 benefit in using a graft.

12 But then we knew -- we knew as surgeons
13 that use graft because obviously there's -- there's --
14 we are -- we are the ones with the largest experience.
15 As surgeons that use graft, we say, well, wait, we have
16 a -- we have different experience using graft. We're
17 not saying that graft are the best for every single
18 case. We -- we understand that. We -- we know -- we
19 know what -- we have a way in our surgical knowledge on
20 how to choose who's going to use it, who's going to
21 benefit from it.

22 But on the -- on the other -- on the
23 other -- on the other side, this -- this graft -- this
24 graft have not been shown to -- shrinkage or the
25 formation, all these things that are being -- that are

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1 being told because we have four -- actually 40 patients
2 followed by ultrasound and four randomized control
3 trials in which it shows that there's no shrinkage.

4 In clinical terms, in very simple terms
5 is we have not seen vaginal shortening. If the patient
6 would have a shrinkage of the mesh and the mesh still
7 there, there should be vaginal shortening -- the vagina
8 would be shorter. And we have not seen that, and we did
9 not see that in Mrs. Cavness.

10 Q. How about degradation. Dr. Margolis talked
11 about -- talked about degradation.

12 A. The -- the deg- -- the degradation, it's --
13 it's a concept that has been shown only on one study. It
14 was done with PROSIMA™. And it was on a study in which
15 the specimen itself was used. The material went through
16 a long process before you could conclude that. There's
17 no actual evidence of in vivo degradation that we can use
18 in our -- to my knowledge, that we can use for clinical
19 use.

20 Q. What's in vivo?

21 A. In a living person, so -- and it's going to be
22 very difficult to obtain that in a living person.

23 Q. Dr. Margolis said that if you used PROSIMA™,
24 you have a higher incidence of a -- of another posterior
25 mesh repair. Has that been your experience?

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1 A. No.

2 Q. Are you aware of any clinical evidence or any
3 literature that supports that?

4 A. No. It -- we -- we have seen with native
5 tissue repairs, repairs with a mesh and without a mesh --
6 repairs with a mesh and without a mesh, there's going to
7 be -- because of the -- of the lack of collagen and
8 content in the tissues, you can see a prolapse. And it's
9 going to come out through an area that is not protected,
10 and the -- so if you protect one area with -- by
11 placing -- placing a graft, you protect that area, the
12 area that is not protected is going to receive pressure.
13 It may prolapse.

14 Q. All these things that Dr. Margolis talked
15 about, things like degradation and the other things he
16 had on his chart, did you see that any of those issues
17 had anything to do with Ms. Cavness?

18 A. No.

19 Q. You know a lot about Ethicon products?

20 A. Yes.

21 Q. And we talked a little bit about this before
22 that you started by attending the cadaver labs or the
23 specimen labs.

24 A. Yes.

25 Q. How long had you -- was it that you'd been

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1 attending before you started teaching in those labs?

2 A. Well, I -- I started attending those -- those
3 labs and placing the instruments, but I would stay
4 longer. I would ask for permission to stay longer on
5 the -- on the cadaver -- cadaver labs. And after
6 everything was placed, I would just dissect the area and
7 make my notes. And it's -- it -- for some -- for a --
8 for a surgeon, it's really difficult to get access to a
9 cadaver lab unless you are in an anatomy department at --
10 at a medical school. So I -- I started doing those --
11 those work.

12 Now, after that, it was -- it was
13 probably a year and a half, two years that they -- they
14 saw me working on it and they asked me would you like to
15 come in, and I wasn't going to start teaching off the
16 bat. You know, I would see how other people taught the
17 lab, and I would help the surgeons that would come in
18 and -- and dissect in the -- in dissecting the cadaver,
19 in dissecting the specimen.

20 Q. When did you start doing that?

21 A. Around I would say the first -- the first few
22 labs, 2003, 2002, maybe earlier.

23 Q. And when you were teaching at these cadaver
24 labs, what's involved in that? I mean, do they come --
25 they don't come to your office?

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1 A. No. It's a lot of work. You travel there.
 2 Q. You travel to where?
 3 A. You travel wherever the lab is being done.
 4 Because not -- you don't have a lab in every community.
 5 You -- you travel to where the lab is. You go to your --
 6 you -- you spend a night in a hotel, and let me clarify.
 7 It's not a luxurious hotel, no.
 8 Their -- their rules and their
 9 guidelines, they're not going to put you in a resort.
 10 So you stay there, and the next day you work, and don't
 11 even think about staying after the lab, about staying
 12 over the night in the hotel, no. They'll get you out,
 13 and you're going home. And obviously when you come
 14 home, then you have your -- your practice that you have
 15 to attend. You have your phonecalls. You have your
 16 other patients that -- that you take care of.
 17 Q. And when you're teaching these labs, tell the
 18 jury what you're doing during the daytime as a teacher.
 19 A. You -- you get up early. You -- you attend
 20 the -- the lectures. You sit there and give -- I like
 21 to -- to give a diagram of this is what we're going to do
 22 to my -- to my two or three doctors that I may have on
 23 the -- on the specimen. This is what we're going to do,
 24 and I -- this is where I'm going to take you, and this
 25 is -- I'm going to show you at the end once you identify

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1 day. It did not include the travel the night before. It
 2 did not include my gasoline, if I drove, or -- and they
 3 did they did cover the airfare. But I can't -- they did
 4 not cover the expenses of my office while I was away.
 5 Q. All right.
 6 A. That's for sure.
 7 Q. And --
 8 A. But I got to dissect cadavers.
 9 Q. Over the years, do you have an estimate as to
 10 about how much you made or were paid for -- by Ethicon
 11 for teaching in these cadaver labs?
 12 A. I -- I -- I got paid on -- on the -- there were
 13 a few -- a few things. I would teach the cadaver lab. I
 14 would be invited to activities where -- where the reps at
 15 Ethicon wanted to learn about cadaver dissection.
 16 Q. Okay. Let's talk about that for a minute.
 17 That's something separate and apart from the cadaver
 18 labs?
 19 A. Right.
 20 Q. Tell the jury what you were doing then.
 21 A. It's a -- when -- when they -- they had
 22 their -- their sales force, the people that was actually
 23 going to be selling the product, they would come in and
 24 dissect with me. And it was a -- a big privilege for
 25 them to be able to dissect with me and the cadaver, and I

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1 all this and I see that you're proficient at it, and I'm
 2 going to -- I'm going to show you how to place it. And
 3 then we can -- we can -- we can -- we can hope to place
 4 the device, and then we can go through it.
 5 Q. Why did you do this?
 6 A. Because it -- it gave me the only opportunity
 7 to interact with my peers at that level. It gave me the
 8 opportunity to dissect cadavers and dissect specimens and
 9 make myself better.
 10 Q. How often did you do these cadaver labs, did
 11 you teach these cadaver labs for Ethicon?
 12 A. They -- there would be -- there would be --
 13 there were years that were like one -- one -- one every
 14 month, and there were times in which it was more frequent
 15 than that. There were times obviously in which was less
 16 frequent, so it change according to the -- I did not
 17 determine how frequent. They would just tell me how
 18 about going to this lab or this other lab.
 19 Q. And what -- what were you paid for teaching an
 20 entire day of these cadaver labs?
 21 A. I -- I got paid, I believe it was \$3,000.
 22 Q. Did it change over the years as to how much you
 23 were getting paid?
 24 A. No. It was -- it was about the same -- the
 25 same rate. It was -- that was for the -- for the full

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1 would teach them, okay, this is where your product goes.
 2 This is how it's used. This is how -- this is how it's
 3 placed. That's -- that's what they wanted to learn.
 4 Q. And those were for the sales representatives?
 5 A. Yes. They could be -- they could be sales --
 6 sales representatives. They could be the engineers.
 7 Q. The engineers. What engineers?
 8 A. There's a -- they're -- they're material
 9 science engineers that --
 10 Q. Who worked for?
 11 A. -- who worked for Ethicon. And they did not
 12 just work on -- on PROSIMA™ or one mesh. They would just
 13 see all this range of material science, and they would
 14 come in and -- and do the lab with me.
 15 Q. What other activities did you do for Ethicon?
 16 A. I -- I also look at their -- at their manuals
 17 to dissect. I look at the -- I put together a book on --
 18 a book on the use of a graft with -- with -- with
 19 diagrams. I -- I would look at presentations. It's --
 20 it's -- it was all -- all these activities I have to do
 21 with -- I publish -- I publish -- we put together a
 22 white -- white paper.
 23 Q. What's a white paper?
 24 A. A white paper is an instructional paper. It's
 25 not an experiment or study. It's a study. White paper

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1 is something we're -- it's a document in which we
2 describe how to get a technique accomplished. And
3 this -- we call it a white paper because there's no
4 statistical summary. It's -- it's an opinion among the
5 among the expert.

6 So we put one that had nothing to do with
7 the device, with any device. It had to do with how to
8 approach the anatomic landmarks on the pelvis with --
9 with minimal blood loss and with accuracy using --
10 letting your -- your solution, your water dissect for
11 you, injecting a solution and then putting everything --
12 blowing everything and then opening and being able to
13 approach all this -- all these areas without blood loss.

14 Q. Is that called hydrodissection?

15 A. I -- I -- I call it hydrodissection. It took
16 off.

17 Q. And you what?

18 A. It took off. Everybody started calling it
19 hydrodissection, and now it's known as hydrodissection.

20 Q. And other doctors use that method?

21 A. For all surgeries, for every surgery. Who
22 wants to -- everybody wants to decrease the blood loss.

23 Q. So going back to over the years that you've
24 worked for Ethicon, can you estimate on average how much
25 money you made per year doing these various activities

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1 and teaching and writing?

2 A. About a hundred thousand dollars a year.

3 Q. Were there years that you made a whole lot more
4 than that?

5 A. I may have done more than in some years that I
6 was -- I was busier. I actually went and checked with
7 my -- when the question came in, I -- I checked with
8 my -- my accountant. I asked him. He could not give me
9 a specific number because I -- I get income from other
10 sources, all the other things that I. Do but from
11 Ethicon, I would say it's safe to say a hundred. There
12 are years that were more. There are years that might be
13 less.

14 Q. But --

15 A. Did I keep track of it? No.

16 Q. And the amount you were paid would just depend
17 on how many activities you were doing, for example, how
18 many cadaver labs you were teaching?

19 A. Oh, you got -- you got to work. If you
20 don't -- you got to put the time. If you don't put the
21 time or work, you don't get paid.

22 Q. And did Ethicon ask you to do these activities?
23 Did they first approach you, or did you approach them?

24 A. No, they approach me.

25 Q. And when did they first approach you?

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1 A. It may -- may be for -- for these activities
2 that involve more. It's -- it was probably after I went
3 to see with the -- with the higher activity after I went
4 to see Professor Cosson in France use transvaginal mesh.

5 Q. All right. Let's get back to Ms. Cavness.

6 THE COURT: Let's go ahead and break here
7 counsel, for about --

8 MS. GALLAGHER: Yes, Your Honor.

9 THE COURT: -- 15 minutes.

10 THE BAILLIFF: All rise for the jury.

11 (Jury out)

12 (Recess taken)

13 THE COURT: Could I have you bring some
14 water for the jurors?

15 MR. CAPSHAW: Yes, sir.

16 THE COURT: I typically ask both sides. I
17 don't know if they sent out the letter this time. They
18 may not have, but I always ask each side to bring a couple
19 of cases of water.

20 MS. GALLAGHER: We have, Your Honor, and
21 we've got more back here.

22 THE COURT: Okay. Wonderful. If we've got
23 more, why don't we just get them.

24 MR. CAPSHAW: Do you want it now, Your
25 Honor?

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1 THE COURT: Yeah. They're out.

2 (Off the record)

3 THE BAILLIFF: All rise for the jury.

4 (Jury in)

5 THE COURT: Take your seats, please.

6 Come on back up and join us, Doctor.

7 You may continue, Ms. Gallagher.

8 MS. GALLAGHER: Thank you, Your Honor.

9 Q. (BY MS. GALLAGHER) Dr. Sepulveda, I want to
10 stitch topics with you for a minute and talk about the
11 information that comes with a device like a PROSIMA™.
12 You're familiar with IFUs, instructions for use?

13 A. Yes. I'm familiar with them.

14 Q. What are those designed for?

15 A. Instructions for use is a guide for the --
16 how -- how the -- the device is placed.

17 Q. Would you expect somebody who has never placed
18 a PROSIMA™ to just open up the package, pull out the IFU
19 and start doing surgery?

20 A. No. I would not expect that.

21 Q. Why not?

22 A. Because you need to -- the -- the device
23 doesn't do the surgery. You do the surgery. You use the
24 device to complete your surgery. So you have to know the
25 details of the surgery before you use that device.

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1 Q. And the IFU contains information about
2 complications and risks?
3 A. It does -- it does mention those -- a few of
4 the complications or potential risks.
5 Q. Is that the only source of information about
6 potential complications and risks of any surgery or the
7 device?
8 A. Absolutely not.
9 Q. Where else do doctors get information from?
10 A. In medical school, in residency, in your
11 fellowship, on your instructions, on the books that you
12 read every time a new edition comes in, and in your -- in
13 your journals, in observing other colleagues, and from
14 your own clinical experience.
15 Q. Have you reviewed the IFU warnings and adverse
16 events?
17 A. I -- I have read -- I have read that in the
18 IFU.
19 Q. Do you think those are adequate to inform
20 surgeons of the potential risks and complications in
21 using a PROSIMA™?
22 A. Yes, they are adequate.
23 Q. Now, who has the duty to inform the patient
24 about potential risks or complications with a surgery or
25 the use of a device?

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1 A. It's -- I am -- I am the surgeon. It's --
2 it's -- it begins and finishes with me.
3 Q. Why is that?
4 A. Because I'm the surgeon. I'm going to be the
5 one performing the procedure. I am in charge of the
6 well-being of that patient.
7 Q. And when you were talking to a patient about
8 the surgery, do you talk to them about things you're not
9 going to do?
10 A. I -- I talk about the things that I plan to do.
11 That's why I do a physical exam and a history ahead of
12 time.
13 Q. If you were not planning on using a particular
14 device with a patient, would you spend the time to talk
15 about that device with the patient?
16 A. There -- there's no -- no reason in this world
17 to overwhelm anyone with an explanation of the surgery
18 that -- or a device that you're not going to use.
19 Q. So you're only going to talk to them about
20 things you are using?
21 A. I'm going to talk to my patient about the
22 things that are relevant to me and are relevant to my
23 patient.
24 Q. All right. Let's get back to Ms. Cavness. I
25 think when we were talking about Ms. Cavness before, we

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1 had gone through why she was in an appropriate candidate
2 under RULES for the surgeries that Dr. Kowalczyk
3 performed.
4 A. Yeah. Yeah. I -- I concluded that.
5 Q. So let's talk about the surgeries went fine?
6 A. Surgery went well.
7 Q. All right. Let's talk about the time period
8 after the surgery.
9 MS. GALLAGHER: And, T-Zady, if you could
10 please pull up 10021.13, and if you could blow up the top.
11 I'm sorry, the reason for visit.
12 Q. (BY MS. GALLAGHER) And, Doctor, you have this
13 on your screen?
14 A. No, I don't have it. I forgot my glasses this
15 morning.
16 Q. Oh. Hold on. I can can fix that. You're
17 going to love these.
18 (Laughing)
19 Q. I do not go anywhere without multiple pairs.
20 THE COURT: It was there momentarily.
21 JUROR: It's not on the screen. His
22 monitor's not working.
23 MS. GALLAGHER: Oh, I thought --
24 THE WITNESS: I said here, here. My
25 monitor's --

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1 JUROR: The screen is not on, working on
2 it.
3 Q. (BY MS. GALLAGHER) You do have glasses?
4 A. Yeah.
5 (Laughing)
6 Q. Do you want the blue ones? You can have the
7 blue ones. I'll wear the red ones, better than not being
8 able to see.
9 A. I need it here.
10 THE COURT: I don't know. It was on
11 momentarily. It just went off. Do you have a clue
12 what's -- what the problem is?
13 THE BAILIFF: No, sir, but that usually
14 fixes it.
15 MS. GALLAGHER: Is this off? Why is that
16 off, do we know?
17 THE REPORTER: Mine's on. Mine's on, and
18 usually they're always off.
19 MS. GALLAGHER: Is yours on, Your Honor?
20 THE COURT: We can -- we --
21 MS. GALLAGHER: How about this?
22 THE COURT: -- we can bring it down and
23 bring it back up.
24 THE BAILIFF: Michael, Michael, usually if
25 you bring the whole system down.

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1 MR. KAUFFMANN: That's what I'm trying to
2 do.
3 THE BAILLIFF: Start over and bring it back
4 up.
5 (Off with co-counsel)
6 MR. KAUFFMANN: Robert, do you think the
7 power could bring it up? The court system's just not
8 starting up.
9 THE BAILLIFF: Shut the whole thing off and
10 start over.
11 THE COURT: Something happened.
12 MS. GALLAGHER: Is it not working?
13 MR. KAUFFMANN: It just takes a second.
14 MS. GALLAGHER: Is it just not going to
15 work?
16 MR. KAUFFMANN: It's in this process.
17 THE BAILLIFF: Hasn't gotten off the screen
18 yet.
19 THE COURT: It's trying to shut down. Are
20 you going to bring it up now, or --
21 THE BAILLIFF: It's not off.
22 THE COURT: Okay. I just wanted to make
23 sure we weren't hitting different buttons at the same
24 time.
25 MR. KAUFFMANN: The spinning hourglass.

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1 Elmo works.
2 MS. GALLAGHER: The issue is their screens.
3 We're fine.
4 JUROR: Doctor.
5 JUROR: Maybe try turning it off and then
6 turning it back on.
7 THE WITNESS: Twice, on -- the connections
8 back here always come loose.
9 JUROR: Oh, got it. Oh.
10 JUROR: Looks like it's loose.
11 JUROR: There was over there.
12 JUROR: There we go.
13 MS. GALLAGHER: It's going on and off.
14 JUROR: It's going on and off up here.
15 JUROR: Yeah, it's a connection over there.
16 JUROR: There it goes.
17 JUROR: And then back on right there.
18 There it is.
19 JUROR: We got it.
20 JUROR: There.
21 JUROR: It's a connection. Yep, a
22 connection.
23 THE WITNESS: Yeah.
24 JUROR: There.
25 JUROR: You can plug --

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1 MS. GALLAGHER: Oh, that's never a good
2 sign, spinning hourglass, Your Honor, sign your
3 electronics are really in trouble. It's --
4 MR. KAUFFMANN: It's making progress.
5 THE COURT: All right.
6 THE BAILLIFF: Never seen it not turn off
7 before.
8 (Judge making phone call).
9 JUROR: Do you guys in the court for the
10 court systems in general, do you have any engineers or
11 technologists?
12 MS. GALLAGHER: I think that might be where
13 he's going.
14 (Off with Coordinator)
15 MS. GALLAGHER: Your Honor, I have hard
16 copies I could hand to the witness and to you, if you want
17 them.
18 THE COURT: We'll just do it the old way.
19 MS. GALLAGHER: All right. Would you like
20 copies of things if I'm going through?
21 THE COURT: If you have them.
22 MS. GALLAGHER: I do, Your Honor, I think.
23 THE COURT: I'll see if I can't get our IT
24 tech up here.
25 MR. MATTHEWS: Ms. Gallagher, I think the

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1 JUROR: You're doing something.
2 JUROR: There it is.
3 JUROR: Yeah, there you go.
4 JUROR: That's it.
5 JUROR: There.
6 JUROR: Stay just -- stay right there.
7 JUROR: So it's right there.
8 MS. GALLAGHER: Michael, you can't move.
9 You have to stay right there.
10 (Laughing)
11 THE WITNESS: Okay.
12 JUROR: I went away again.
13 THE COURT: All right. We'll see what we
14 can have done at lunch.
15 MS. GALLAGHER: Is it not working? Okay.
16 MS. GALLAGHER: Are you ready?
17 THE REPORTER: Yeah.
18 Q. (BY MS. GALLAGHER) Doctor, given our technical
19 difficulties, you can't see it on the screen, so I've
20 just handed you the actual -- a paper copy of the record.
21 Do you see this?
22 A. I do.
23 Q. And in this record, this is the first time
24 that Ms. Cavness comes back after having had her various
25 surgeries with Dr. Kowalczyk; is that right?

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1 A. Yes.

2 Q. All right. And she's coming in at this time

3 for what reason?

4 A. She's coming for a postop examination after

5 posterior repair, plication and PROSIMA™.

6 Q. And what is her issue?

7 A. The patient -- Dr. Kowalczyk documents that

8 Mrs. Cavness felt a foreign body in the vagina.

9 Q. And what is she feeling?

10 A. The vaginal support device.

11 Q. Tell the jury what the purpose of the vaginal

12 support device is.

13 A. The -- once -- once you place an im- -- this

14 implant for PROSIMA™ specifically, for PROSIMA™, and the

15 implant sits in there, there's -- there's no actual

16 sutures or attachment to it. So -- so when -- since it's

17 tension-free, we call that tension-free, and tension-free

18 in general means that a -- the -- the -- graft is not

19 being distorted on its normal shape. That's one of the

20 requirements for tension-free.

21 But while -- when the patient -- when the

22 patient stands up and she starts walking around, your --

23 the -- this -- the vagina will move. And the -- the

24 pressure -- the abdominal pressure that we all generate

25 when we walk around and when we -- when we move, we

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1 just -- we just move the graft. So it takes about three

2 to four weeks for the tissue to -- to get a

3 nice ingrowth in between the pores and around the small

4 fibers.

5 It takes it takes about 21 to 28 days, so

6 the vaginal support device stabilizes the graft, and

7 it -- it allow -- it -- it allows for me to place the

8 graft without putting a suture to hold it. That's --

9 it's -- it holds the graft in place with all --

10 regardless of the other movements that the patient may

11 have on doing her dale -- doing her activities.

12 Q. And did Ms. Cavness have any issues with the

13 vaginal support device staying in place postoperatively?

14 A. No.

15 Q. Was there a time when Dr. Kowalczyk had

16 to replace a suture?

17 A. There was one suture that came loose. It -- it

18 happens when the suture comes off from where it has been

19 placed to hold -- to hold the vaginal support device.

20 Q. And that's my question. The suture that

21 Dr. Kowalczyk replaced for the vaginal support device had

22 nothing to do with the actual PROSIMA™?

23 A. That's correct.

24 Q. Now, I want to talk to you about the explant

25 surgery that Dr. Carley did. But I want to talk to you

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1 about something that was happening before that in June.

2 Do you recall that it was early June when

3 Ethicon announced the de-commercialization of PROSIMA™?

4 A. I -- I recall that.

5 Q. Well, what was the reaction? Describe that

6 period for you as a urogynecologist.

7 A. Well, it's -- we -- we had -- we had an option

8 in the patients that -- we had an option --

9 MR. MATTHEWS: Judge, I would object as to

10 relevancy. This was post-implant -- explant.

11 THE COURT: What's the relevance of that?

12 MS. GALLAGHER: Your Honor, it's going to

13 go to his perceptions of a tunnel vision that a lot of

14 uro- -- or gynecologists had after that of problems with

15 mesh. It goes to the whole looking -- the differential

16 diagnosis of the various doctors going through the rest

17 of Ms. Cavness's chronology.

18 THE COURT: Sustained.

19 Q. (BY MS. GALLAGHER) Doctor, let's move to the

20 July 2012 explant that Dr. Carley did. All right. And

21 can you tell the jury just generally what surgeries

22 Dr. Carley did?

23 A. He -- Dr. Carley went ahead and removed the --

24 the implant, and during the removal of the implant, he

25 identified defects that -- the defects in the area, the

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1 prolapse. He identified the prolapse, and he went ahead

2 and sutured this, and did a suture repair with -- with a

3 non-absorbable suture.

4 Q. And explain to the jury the difference between

5 nonabsorbable, absorbable and absorbable sutures.

6 A. Oh. We -- we have a -- we have in our trades,

7 we have sutures that are absorbable. They're absorbable,

8 means that they would disappear. The fibrosis will

9 take -- will take over for the force of the suture. We

10 have sutures of different calibers. We have sutures that

11 are nonabsorbable, and we have sutures that are with

12 multiple filaments, very tiny filaments put together.

13 And we have sutures that are just one filament, one --

14 one single filament.

15 Q. And are some of those sutures designed to stay

16 in the body forever and some go away?

17 A. Some of them are going to stay, you know, stay

18 forever. And they're going to -- they're going to be

19 adapting to the body, and they will stay there, and some

20 of them are absorbable.

21 Q. Explain to the jury the procedure that

22 Dr. Carley used to remove the mesh from Ms. Cavness.

23 A. Dr. Carley opened the -- the vag- -- the

24 vaginal covering using over -- over the implant and

25 dissected it out, and that's -- that's a very -- that's a

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1 very standard procedure, dissected it out and then went
2 through this arm and this arm, and he describes that
3 he -- he pull it and pulled the implant out.

4 Q. Did he do that in one piece or more than one
5 piece?

6 A. He -- I checked the pathology report, and
7 although he does not describe in his operative report
8 that it was in one piece or multiple pieces, the
9 specimen, what comes out is in multiple pieces.

10 Q. Now, Doctor, you talked about the surgery that
11 Dr. Carley did afterward.

12 A. Yes.

13 MS. GALLAGHER: And, Your Honor, can I have
14 him come down and draw this?

15 THE COURT: You may.

16 Q. (BY MS. GALLAGHER) And, Doctor, you're going
17 to have to have me hold this because I lowered these for
18 the timeline, so maybe we can prop it up here. Can I get
19 another color?

20 (Off with co-counsel)

21 Q. Okay. Go back to our blue woman. I'll hold
22 it, if you'll draw.

23 A. Do you have a green one?

24 Q. I think you have the green one up there. Up
25 there --

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1 eventually come down in here.

2 So when you -- what you do is with the
3 uterosacral ligament suspension is you go higher, and
4 then you put a stitch on top of here. And that's --
5 there are two stitches on those that he placed up --
6 permanent suture.

7 Q. And that's what you're doing in the green
8 marker?

9 A. In there, and, yeah. So -- and there -- and
10 there -- and I'm putting the stitches up, and I'm
11 bringing it down, and then when you cinch them down, what
12 you have left is this, this suture, but there are more
13 than just two sutures. There were another -- I'm not --
14 I'm not going to put a loop. I'm just going to put a
15 line --

16 Q. Okay.

17 A. -- with these sutures. One -- one suture from
18 here, here to here, and a suture is a stitch, and one
19 from here to here, here -- another one from here into
20 here. And the last one is a permanent suture. These
21 were absorbable permanent sutures right here, and the
22 same thing happened on the other -- on the other side.

23 Q. So --

24 A. There was a suture from here, and then there
25 were three other sutures that were absorbable. So the

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1 A. Oh, there.

2 Q. -- by my glasses --

3 A. Yeah.

4 Q. -- that you're refusing to use.

5 (Laughing)

6 A. Just green one.

7 Q. Okay. So first, if you would, would you draw
8 in where the mesh was originally placed?

9 A. It was placed this -- it was placed right
10 around here, here to here.

11 Q. All right. Now, the surgery --

12 A. That's -- that includes a little arm like this
13 and might be a little shorter than that space on basic
14 description.

15 Q. Now, would you explain to the jury the -- is it
16 a USL, uterosacral ligament suspension, that Dr. Carley
17 performed after he removed the mesh?

18 A. He removed the mesh, and now he sees that
19 there's a prolapse right -- right up here on the upper --
20 on the upper third of the vagina, in the upper
21 two-thirds. This is the rectum. This is the vagina, and
22 it's right here, right in here. And then he sees that
23 this is coming down, and that this vaginal cuff was going
24 to come down, and it's like -- if you take one of your --
25 of your socks and invert it out, you know, it would just

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1 whole -- all this -- all this is covered. Three -- three
2 sutures on one side and six sutures in total of the
3 vaginal cuff with three sutures on each side.

4 Q. Now, Doctor, in order for Dr. Carley to get to
5 this area to put the sutures, all right, where is he
6 going through to do this?

7 A. Well, you -- to get to the next building, you
8 have to cross the street, and the street is basically the
9 spine --

10 Q. All right.

11 A. -- across -- the mesh was -- the mesh was here,
12 and you can -- you can count on the -- on the mesh. You
13 can could 6 centimeters maybe, mesh in here, but you have
14 to get up here. So -- but that's -- the inserter doesn't
15 let you place the mesh longer than 10 centimeters in.

16 Q. Which would be where?

17 A. At the level of the ischial spine.

18 Q. And where is the ischial spine?

19 A. Right here. But you have to go higher than
20 that to put the stitches.

21 Q. And when you say go higher than that, are you
22 staying on the same plane?

23 A. Yes. You're go on the same plane. You open --

24 Q. Describe to the jury what that means.

25 A. When you're looking -- look at it -- this the

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1 floor of the vagina. You're going in this plane, and
 2 then you go up and dissect it out, and that's what is
 3 called areolar connective tissue, is very thin tissue
 4 that just opens up.
 5 Q. So first Dr. Carley removed the mesh?
 6 A. Right.
 7 Q. All right. And then after he removed the mesh,
 8 did he have to go through the exact same area to do the
 9 USL sutures?
 10 A. That's a suture -- that's a suture that the
 11 other sutures that came in the -- when he was going
 12 to repair the enterocele and the rectocele, it comes out
 13 like this with our suture. That's the green suture.
 14 Q. And you've drawn that in the green. Why?
 15 A. Because the suture is green.
 16 Q. Is that a permanent or an absorbable suture?
 17 A. That's a permanent suture.
 18 Q. All right. So tell jury where -- just
 19 summarize where are the permanent sutures and where are
 20 the absorbables.
 21 A. There's a permanent suture right here on the
 22 division of the rectum and the vagina. And there's a
 23 permanent suture on each side of the uterosacral
 24 ligaments, on each side, one to here and one to here.
 25 Q. Thank you, Doctor. Now, when Dr. Carley did

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1 far I can go with this instrument. Now, I have explained
 2 already that the instrument comes right here, so it's not
 3 like I can just take it and just shut -- put it up there.
 4 Actually, it's made in a way that is not sharp. It's
 5 made in a way that is not sharp. You cannot -- you
 6 cannot really go as far.
 7 So you cannot go longer than 10
 8 centimeters. It's not like you're penetrating anything.
 9 So when you do a high uterosacral ligament suspension,
 10 you're going higher than that. You're going higher than
 11 your 8, 10 centimeters. The uterosacral suspension is
 12 up here.
 13 So to get the mesh, all you have to do is
 14 get your finger and you get right to the tip of the
 15 mesh. All you have to get is to get your finger up.
 16 This idea that there's a mesh lost somewhere or embedded
 17 somewhere, that's not true. I can get it to my finger,
 18 and that's -- that's the distance.
 19 Q. How pathology slide that measures it at by four
 20 by three or whatever the pathology measurement is?
 21 A. So this is what happens. You have your implant
 22 in place. It's surgically inconceivable that I'm just
 23 going to take this and just take it like this because
 24 that -- and in one piece. It needs surgically
 25 inconceivable because there's an interaction of tissue,

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1 the explant, the mesh removal, did he think he got it
 2 all?
 3 A. Yes.
 4 Q. Now, the jury has seen a diagram where there's
 5 a picture of the PROSIMA™ that's actually bigger than a
 6 real PROSIMA™, and it's got a little square cut out of
 7 it. You -- you've seen that?
 8 A. Yes.
 9 Q. All right. Explain to the jury why you think
 10 Dr. Carley got all the mesh.
 11 A. I -- I -- my opinion is that there are --
 12 there's more than one -- one reason why he got it all.
 13 Number one is you look at the measurements of PROSIMA™.
 14 In between -- between each blue line is 2 centimeters, so
 15 there's 1, 3, 5, 7 centimeters, and it's 7 centimeters up
 16 to here. Then you have another two plus maybe one here.
 17 So it doesn't go beyond 10 centimeters.
 18 Let's say the PROSIMA™ will be longer
 19 than 10 centimeters. You cannot insert it longer than
 20 10 centimeters with this inserter. The inserter doesn't
 21 go deeper. It can -- the inserter cannot go -- cannot
 22 come in here if it -- if it stops right here, so --
 23 Q. Why is that significant? Explain that to the
 24 jury.
 25 A. That is significant because it speaks about how

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1 and you want that when you place an implant. You have an
 2 interaction with the tissue.
 3 More importantly, this surgery was done
 4 at 7:00 in morning. The operating report is dictated at
 5 7:09, at 7:09, and the specimen is reported as examined
 6 at 5 o'clock. Now, this is not like the -- the -- it
 7 was perfectly preserved. That -- that mesh has tissue
 8 inside, so now you're going to drop it. Now, you're
 9 going to drop in formalin.
 10 Q. What is formalin?
 11 A. Formalin is a desiccating agent.
 12 Q. What is a desiccating agent?
 13 A. It takes all the water and contracts the
 14 fibrous tissue. So now you're going to put this specimen
 15 on formalin at 7:00 in the morning and now at 5 o'clock,
 16 you're going to expect to take something out, and you
 17 expect everything to be unfold. It's not -- it's not
 18 possible. There's tissue in between each pore. This --
 19 this mesh was well-incorporated. It was -- it would have
 20 tissue in the pores, and when the tissue desiccated, it
 21 brought it down, and in every single specimen, you're
 22 going to see that that tissue contracts. The tissue
 23 contracts. Just -- you just place it for that period of
 24 time on formalin 50 percent.
 25 Q. Now, Doctor, after the explant, did Ms. Cavness

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1 continue to have problems?

2 A. She -- she continue with -- with pain. There
3 were no issues with the mesh.

4 Q. In September, did she have to have -- 2012, did
5 she have to have a suture removed?

6 A. That's correct.

7 Q. Explain to the jury what was involved in
8 removing that suture and where that suture came from.

9 A. After that surgery in which that suture was
10 placed, there's an office note in which a green suture
11 was removed from the area where it has been placed in
12 the -- in the vagina.

13 Q. And is that the same green suture -- one of the
14 same green sutures that you drew on this diagram?

15 A. Yes.

16 Q. All right.

17 A. It's -- no. The green sutures is -- is
18 specifically the one that was placed right down here.
19 You cannot access these ones up here. You can access
20 only the one is down here.

21 Q. Ms. Cavness had another surgery in April of
22 2013.

23 A. Yes.

24 MS. GALLAGHER: And, T-Zady, if you could
25 pull up, please, 1004.123.

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1 (Off with co-counsel)

2 THE COURT: Folks, let's just let that hang
3 there. I've got the -- I think the AV guy from the County
4 over here. We're going to take lunch right now, so I'm
5 going to see you at 10 after 1:00, see if we can get this
6 fixed.

7 THE BAILIFF: All rise for the jury.

8 (Jury out)

9 (Recess taken)

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1 STATE OF TEXAS)

2 COUNTY OF DALLAS)

3 I, Deana K. Rouse, Official Court Reporter in
4 and for the 95th District Court of Dallas County, State
5 of Texas, do hereby certify that the above and foregoing
6 contains a true and correct transcription of all portions
7 of evidence and other proceedings requested in writing by
8 counsel for the parties to be included in this volume of
9 the Reporter's Record in the above-styled and numbered
10 cause, all of which occurred in open court or in chambers
11 and were reported by me.

12 I further certify that this Reporter's Record
13 of the proceedings truly and correctly reflects the
14 exhibits, if any, offered by the respective parties.

15 I further certify that the total cost for the
16 preparation of this Reporter's Record is undetermined at
17 this time.

18 WITNESS MY OFFICIAL HAND this 30th day of
19 September, 2015.

20
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